

Should Canada allow direct-to-consumer advertising of prescription drugs?

NO

Barbara Mintzes PhD

Direct-to-consumer advertising (DTCA) of prescription drugs has increased enormously over the past decade in the United States and New Zealand, the 2 countries where it is legal. In 2005, more than \$4.2 billion (US) was spent on DTCA in the United States,¹ and Americans spent an average of 16 hours watching televised drug advertisements—far more time than they spent with family doctors.

Market research company IMS Health reviewed the returns on investment in DTCA for 49 brands from 1998 to 2003 and found that for “blockbuster” drugs, such as rofecoxib, companies on average obtained \$3.66 per dollar invested.² The key controversy is not whether DTCA stimulates sales, but whether or not this is good or bad for health, health care quality, and total health care costs.

Direct-to-consumer advertising of prescription drugs is prohibited in Canada as a health protection measure. Manufacturers cannot advertise prescription-only drugs directly to the public because of their toxicity and the potential for harm from medically unnecessary or inappropriate use. Any debate over DTCA, however, must address enforcement. Despite its illegality, exposure to cross-border and, increasingly, “made-in-Canada” ads is widespread. Just because such ads are allowed in the United States, cross-border DTCA on US cable television is not inevitable. It is technically simple to replace US ads with local advertising. Similarly, “made-in-Canada” DTCA could be prevented under current laws—the question is one of political will. Succumbing to heavy pressure, Health Canada reinterpreted a 1975 price advertising regulation to allow one type of DTCA, branded “reminder” advertising, in 2000.³

Negative effects

In a Vancouver, BC, study of primary care, patient requests for advertised drugs affected prescribing volume and choice (albeit less strongly than in a US setting, a reflection of lowered exposure).⁴ In a 2002 survey of health professionals in Canada (N=1975), 67% of GPs reported sometimes or often feeling pressured to prescribe advertised

drugs.⁵ By portraying various medicines as a 100% effective solution to an array of life problems, DTCA turns doctors into gatekeepers for desired brands.

The 2006 tegaserod ad for irritable bowel syndrome is emblematic of the hazards of prescription drug advertising. The eye-catching ad featured women baring their bellies to reveal slogans. Closing shots panned women of many different ages and races, suggesting widespread use. Relief of vague symptoms along with a comparison to fibre and laxatives implied use for mild problems. But key information on safety concerns, limited effectiveness, and the limited appropriate patient population was lacking. In 2007, the drug was withdrawn from the market because of cardiovascular risks. The first Food and Drug Administration safety warning, on risks of ischemic colitis, dated back to 2004. Tegaserod prescriptions rose by 56% in a US Medicaid population and 42% in English speaking Canada following exposure to US DTCA campaigns.⁶

The 2004 market withdrawal of rofecoxib had already raised red flags about DTCA's ability to rapidly stimulate sales of new drugs with emergent serious risks. Rofecoxib led to an estimated 88000 to 140000 heart attacks in the United States, 44% of which were fatal.⁷ It was among the most heavily advertised drugs for 4 years after the first large-scale clinical trial showed evidence of cardiac risks. In a Kaiser Permanente study, 20% of initial users of cyclooxygenase-2 inhibitors had requested prescriptions after seeing ads.⁸ These users were 4 times as likely as other users to be inconsistent with treatment guidelines.

Because of its focus on new, expensive drugs, DTCA drives up consumer costs. In New Zealand, DTCA for fluticasone asthma inhalers fueled broad substitution for beclomethasone, which is equally effective and less costly. More than \$1 billion (US) was spent on US DTCA for esomeprazole; yet the same treatment effects can be achieved with generic omeprazole. Most new drugs have no therapeutic advantage over existing alternatives, and new serious risks are often discovered in the early postmarketing period. From a public health perspective, caution, not rapid uptake, is needed.

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The parties in this debate refute each other's arguments in rebuttals available at www.cfp.ca. Go to the full text of this article on-line, then click on **CFPlus** in the menu at the top right-hand side of the page.

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Social control

Is opposition to DTCA paternalistic? Independent consumer groups reject this claim, arguing that DTCA fails to provide the unbiased, comparative information needed for shared and informed treatment choices. Key information, such as the probability of treatment success, is usually missing. Instead, emotive messages dominate: in a sample of television ads, drug use was associated with happiness in 95% of ads, control over one's life in 85%, and social approval in 78%.⁹ The US regulatory experience is also instructive—of 135 ads violating US law from 1997 to 2005, 84% minimized risks or exaggerated benefits.¹⁰

Direct-to-consumer advertising of prescription drugs affects prescribing volume and choice.¹¹ In one study, physicians prescribed most DTCA drugs patients requested, but were 8 times more likely to judge those drugs as only “possible” or “unlikely” choices for similar patients than “very likely” choices.⁴ In an experimental study, patient requests led to twice as many antidepressant prescriptions for patients with depression and a 5-fold increase for patients with “adjustment disorder,” which does not require drug treatment.¹² Patient requests were a stronger predictor of prescriptions than symptoms.

Undertreatment of depression is often cited as a problem DTCA could help solve, as population surveys have identified many untreated people who meet *Diagnostic and Statistical Manual of Mental Disorders*, 4th edition, criteria. A Canadian survey compared people with depression taking antidepressants with those not taking antidepressants (N=9508).¹³ Half of those not taking antidepressants recovered within 5 weeks. Mean episode duration was 11 weeks versus 19 weeks for those taking antidepressants. Bottom line, many of the so-called “undertreated” patients might not actually require drugs.

Direct-to-consumer advertising can and does cause harm. Any benefits could be better achieved through public health campaigns. The law prohibiting DTCA remains valid, but needs better enforcement. A simple start is to repeal the price advertising regulation to eliminate reminder ads.³

If money is power, DTCA is indeed empowering. The question is, for whom and at what cost to the public and to medication as a social good?

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Competing interests

Dr Mintzes was a consultant to the Federal Department of Justice for the legal case in the Ontario Superior Court, in which CanWest MediaWorks challenged the prohibition of direct-to-consumer advertising of prescription drugs in the Food and Drugs Act.

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CLOSING ARGUMENTS

- Direct-to-consumer prescription drug advertising can cause damage by instigating rapid, widespread stimulation of use of new drugs before harmful effects are fully known.
- Advertisements exaggerate treatment benefits and use emotive messages to target people with milder health problems, many of whom are unlikely to benefit from the drugs advertised.
- Advertising leads to higher drug costs and overall health care costs through substitution of new, expensive drugs without treatment advantages.
- Better enforcement of direct-to-consumer advertising laws in Canada is needed.

