CanWest's Charter Challenge on prescription drug advertising: A Citizens' Guide

In December 2005, CanWest Mediaworks filed a lawsuit against the federal government, charging that Canada's prohibition of direct-to-consumer advertising (DTCA) of prescription drugs is an unjustified infringement of the company's freedom of expression, as guaranteed under Section 2(b) of Canada's Charter of Rights. The case is being heard in the Ontario Superior Court. It is Health Canada's responsibility to defend the current law against DTCA. Cross-examination of expert witnesses is expected in the fall of 2006, with final pleadings from both legal teams in December or January.

Why prohibit direct-to-consumer advertising of prescription drugs?

- Prescription drugs are not like other consumer goods. Even when used properly, they can cause serious harmful effects, sometimes even death.
- Advertising does not provide the impartial, objective information consumers need to make informed health choices. Its main goal is to increase product sales.
- A sick person is not like someone shopping for a new perfume or car. People are vulnerable when they are ill and often have to make difficult treatment choices.
- Companies almost always advertise their newest products to gain market share and recoup development costs. Many new drugs are no safer or more effective than older drugs, but are costlier. Often little is known about rare or long-term risks.
- Advertising of medicines promotes unnecessary medicalisation of normal life. Drug treatment for baldness, restless legs, shyness, toenail fungus, pre-menstrual syndrome, or occasional sexual problems may do more harm than good.
- Studies show that the doctors who rely more on information from drug promotion prescribe less appropriately. Similarly, promotion aimed at the public is likely to lead towards less appropriate medicine use.
- Prescription drug advertising drives up health care costs.

Prescription drug advertising to the public is legal in only two countries, the United States and New Zealand. Like most other countries, Canada prohibits DTCA as a health protection measure. The aim in restricting both sales and advertising is to prevent inappropriate medicine use that could result in harm.

CanWest is arguing that the current law places the company at a competitive disadvantage to U.S. media because it cannot sell advertising space to drug companies. The industry spent US$4.8 billion on DTCA in the U.S. last year. If even one-tenth as much was spent in Canada, it would amount to over CDN $500 million. That's likely to amount to a lot of advertising revenue for Canada's biggest media company.

This guide discusses the background to this legal case, the implications for Canadians, and what you can do.

The Legal Case

Fundamental to this legal case is the courts' interpretation that Charter rights of free expression apply to a corporation as if it was an individual living person. But what if there is a conflict between the rights of a corporate "person" and basic human rights? We believe that DTCA threatens the quality and equity of healthcare services and undermines the right to protection from harm of vulnerable individuals – those facing serious illness. In the hierarchy of rights, do the rights of the corporate "person" trump the public's right to health and safety, especially those individuals who are most vulnerable?

Who is CanWest?

CanWest is Canada's largest media company, formed in the 1970's by Winnipeg businessman Izzy Asper and still controlled by the Asper family. The company owns 65 TV, radio, print and on-line media outlets, including Global TV, a network of specialty TV stations, and most major newspapers in Canada, including the National Post, the Montreal Gazette, the Calgary Herald, the Ottawa Citizen, the Vancouver Sun and Province and a host of others. CanWest also owns the free commuter papers Dose and Metro, many local weeklies, and several magazines, including Financial Post Business magazine. The company says on its website that 96% of Canadians have access to its TV stations and that its print media reach 4.4 million people. CanWest also owns a TV station in Australia and two in New Zealand, and radio stations in Turkey and the UK.

CanWest Mediaworks presents two main arguments:

- Advertising is allowed for medicines a person can buy themselves in a drugstore (over-the-counter drugs) such as aspirin, cough and cold remedies, and antidiarrhoeals, even though these drugs also have risks;
- U.S. DTCA for prescription drugs is allowed in U.S. magazines and newspapers that are sold on Canadian newsstands.

The first argument ignores why some drugs have prescription-only status and why others can be sold directly without a prescription. Drugs with prescription-only status are generally more hazardous, have less well-understood harmful effects, or are for serious health conditions requiring a doctor's care. Most over-the-counter drugs are for common problems such as headaches and colds that people generally treat on their own.

The second argument is based on the current law against DTCA being inadequately enforced. Public interest and consumer groups have been raising concerns about the lack of adequate enforcement for around ten years – since U.S. loosening of restrictions on broadcast ads led to a flood of cross-border advertising. This has been a huge problem, made worse by inadequate sanctions for 'made-in-Canada' illegal advertising. However, the solution to inadequate enforcement is not necessarily to change the law. If some drivers get away with speeding, should speed limits be eliminated? Another option is to strengthen enforcement.

Why has CanWest launched this case?

CanWest is not prevented from running editorial content or television programming on drugs under current law. Only prescription drug advertising is banned. This case is about the company's ability to sell advertising space.

Drug companies, not the media, are being prevented from advertising their products. Why aren't they suing the government? In a 1996 briefing paper to Health Canada, Merck Frosst argued that the ban on DTCA was an infringement of drug companies' freedom of expression, as guaranteed under the Charter. This argument was based on a 1996 decision on tobacco advertising.

Since then, no drug company has launched a Charter Challenge on DTCA. Perhaps this is because it would be a public relations disaster if pharmaceuticals were linked to tobacco as the two industries that challenged public health restrictions on advertising.

Prescription drug advertising raises important safety concerns because of its effects on medicine use:

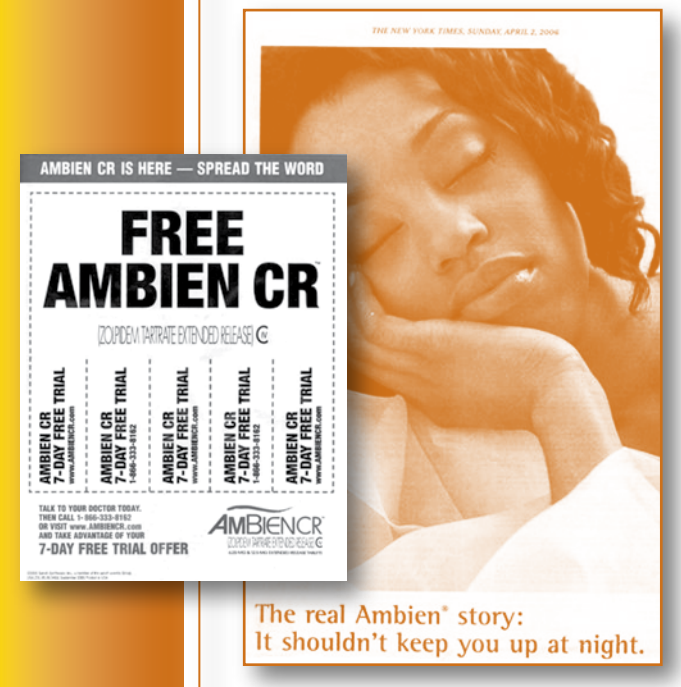
- Rapid uptake of new drugs before their longer-term and/or rare risks are fully known
- Increased use of 'lifestyle' medicines among the healthy
- Treatment of increasingly mild forms of common chronic illnesses
- Increased drug use, leading to higher rates of polypharmacy (use of many medicines per person)
- Increased rates of physician prescribing in response to patient demands, even when physicians are ambivalent about the treatment decision
- Increased prescribing for unapproved uses ("off-label" prescribing)

These shifts in medicine use also lead to higher costs:

- Use of expensive new drugs when cheaper alternatives are available
- Increased overall prescribing volume
- Increased consultation rates with physicians for conditions not previously considered medical
- Use of many medicines per person (polypharmacy), leading to more adverse drug reactions and, as a result, more physician and hospitalization costs. (Large-scale safety studies show a strong link between the number of drugs a person takes at the same time and risk of adverse drug reactions.)

A major threat to Medicare

Drugs are the fastest growing healthcare cost. With DTCA their costs will grow much faster, threatening the sustainability of publicly funded healthcare. In the first year of full DTCA in Canada, the industry is predicted to spend CDN$500 million. Market research on effects of DTCA in the U.S. suggests that this will lead to at least $1.1 billion in extra sales. That's $1.1 billion of extra drug costs for Canadians.



If CanWest wins their case, we could be seeing ads like this regularly.

Private as well as public payers will be affected. About half of working people in Canada get extra health care coverage through employer-sponsored health plans. Prescription drugs are the biggest cost component. In a recent survey of employers across Canada, 95% said rising health care costs were their number one concern. DTCA will increase that strain, leading employers to pass on extra costs to employees through higher premiums, cut drug coverage, or abandon employee health plans altogether.

No net benefits

There is no reliable evidence that prescription drug advertising leads to better health or health care quality. DTCA has not been shown to improve patient-doctor relationships, rates of medically necessary diagnoses, or the quality of prescription drug use. There is no evidence of reduced hospitalization costs or other health care savings.

Does DTCA inform and empower the public?

One of the key claims made in favour of DTCA is that it informs the public about available treatments, and empowers patients to share in treatment choices. But evidence from systematic reviews of advertising content, the quality of information in the ads, and the regulatory history to date in the U.S. and New Zealand consistently show poor information quality:

- Key information needed for informed treatment choice is usually lacking, such as the likelihood of treatment success, other available options, costs, etc.
- The U.S. FDA regularly finds DTC ads to violate U.S. law, usually because they minimize risks, exaggerate benefits or promote off-label uses.
- Advertising fails to inform the public of all available treatments. Only new on-patent expensive drugs for longer-term use tend to be advertised.
- DTCA offers individual drug solutions – with unrealistic images of effectiveness – for many problems with social causes, such as PMS medication for women who are overtaxed by having too many jobs. This diverts attention and resources from approaches that could lead to real solutions.

Canadians need complete, accurate and reliable information about all available treatments, both drug and non-drug. Advertising is designed to increase sales of a specific product and does not meet this need.

Has DTCA led to harm? A few examples

- **Stimulating widespread use of newer drugs before risks are fully known.** From 1999 to 2004, Merck spent $550 million advertising the arthritis drug Vioxx (rofecoxib) to the U.S. public. There was evidence of increased heart attack risks from a large trial published in November 2000,[1] and Vioxx had never been shown to be any more effective than cheaper alternatives.[2] David Graham, a senior FDA official, estimated that 35,000 to 45,000 Americans died from heart attacks due to Vioxx use,[3] based on results of clinical trials, the rate of use, and the death rate for heart attacks. Based on market research reports on returns on investments for DTCA,[4] around one quarter of Vioxx sales were from TV and print advertising to the public. This translates to around 10,000 avoidable deaths.

- **Unrealisticimages of effectiveness can lead to unwise choices.** The San Francisco Public Health Department found that gay men who had seen more ads for HIV/AIDS drugs were more likely to report having had unprotected sex in the last month and to believe that HIV/AIDS was a less serious syndrome.[5] In another U.S. study, people with insurance covering drug costs were more likely to report that they smoked when there was heavy advertising of drugs to quit smoking; they were less likely to say they exercised when ads for weight loss, cholesterol or blood pressure lowering or diabetes drugs were running.[6] The ads present drugs as a simple, almost magical solution to many health problems, apparently eliminating the need for lifestyle or social changes.

- **Overuse ofmedicines for day-to-day problems.** In 2005, there were 60% more prescriptions for sleeping pills in the U.S. than in 2004. Two sleeping pills were heavily advertised, Ambien (US$130 million) and Lunesta (US$215 million).[7] Like other sleeping pills, these drugs can cause dependency, higher rates of traffic accidents, falls and fractures and mental deterioration in the elderly. One in 6 people over 60 using sleeping pills suffers harm; only 1 in 13 does better than someone on a placebo ('sugar pill').[8]

- **Highercosts but no better value.** Many heavily advertised drugs have no health advantage over cheaper alternatives. Increased sales of the 20 most heavily advertised drugs in 2000, representing almost all DTCA spending, were responsible for nearly US$10 billion of the $20.8 billion increase (48%) in U.S. retail prescription drug costs between 1999 and 2000.[9] All of these drugs are covered by patent protection. Astra Zeneca spent US$1 billion advertising Nexium (esomeprazole) to the U.S. public during the last 5 years. What the ads did not say is that Nexium, a patented drug used to treat gastric reflux, is essentially the same chemical as omeprazole (Losec or Prilosec), with the same effect at equivalent doses.[10a] Generic omeprazole is much cheaper.

[a] Nexium (esomeprazole) is an isomer of Losec (omeprazole). Losec consists of the same molecule with two different orientations in space (a racemic mixture), like a right and left hand. Nexium has only one orientation in space (a single isomer, part of the mixture in Losec). It is not really a different drug.

The bottom line: freedom of expression or freedom to sell advertising?

CanWest is not prevented from running editorial content on drugs under current law. Only prescription drug advertising is banned. CanWest's Charter challenge calls upon the court to choose among competing public policy objectives: Canadians' right to health and safety versus a corporation's right to sell advertising. To protect the public good, public health and safety rights ***must*** trump a corporation's right to sell advertising.

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What can you do to prevent the legalization of DTCA in Canada?

- **Tell your Member of Parliament and the Health Minister** that you support the current provisions in the law that make DTCA illegal and that you do not support CanWest's position.

  The Honourable Tony Clement, Minister of Health, can be contacted at:

  Minister's Office - Health Canada
  Brooke Claxton Building, Tunney's Pasture
  Postal Locator: 0906C, Ottawa, Ontario, K1A 0K9
  Fax: (613) 952-1154
  E-mail: Minister_Ministre@hc-sc.gc.ca

- **Let your provincial Minister of Health know** that you are concerned that CanWest's case is threatening provincial healthcare services.

This booklet was written for Women and Health Protection. For more information about Women and Health Protection and to download a copy of this guide, please visit our website at www.whp-apsf.ca.

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