

## Direct-to-Consumer Prescription Drug Advertising Health Canada's Proposals for Legislative Change

Canadian Health Coalition and Health Action International (HAI-Europe), January 2004

Canada currently forbids advertising of prescription drugs to the public, as do all other countries except the United States and New Zealand. This restriction on advertising is part of the protection offered to the public by prescription-only status.

Last June, the Health Minister announced a proposal to replace the federal Food & Drugs Act with a new Canada Health Protection Act. This proposal includes two key changes to the law governing advertising of health care products: introduction of direct-to-consumer (DTC) advertising of prescription drugs and elimination of a list of serious diseases (Schedule A diseases) for which manufacturers may not advertise treatments, preventatives, or cures to the public. (Health Canada, 2003)

Several options are on the table, including both partial and full elimination of existing limitations on manufacturers' rights to advertise medical treatments. However, even partial deregulation would represent an important 'foot in the door' for DTC advertising in Canada.

What will these changes mean for public health, for sustainability of health care services, and for consumer and patient information rights?

This paper discusses the proposed changes, reviews the main evidence on effects of DTC advertising in the US and New Zealand, and concludes with recommendations.

### Why maintain the current ban on direct-to-consumer (DTC) advertising of prescription drugs?

- **DTC advertising drives up prescription drugs costs**, threatening the sustainability of national health care services and universal access to health care as a fundamental human right.
- **DTC advertising fails to inform**. It does not provide the impartial, objective information consumers and patients need for informed health care decisions.
- **DTC advertising compromises public safety**. It can lead to rapid widespread exposure to dangerous drugs before risks are fully recognized, as occurred with troglitazone (Rezulin) for diabetes and cisapride (Propulsid) for nighttime heartburn in the US. Additionally, most new drugs are costlier than existing treatments, but few provide any therapeutic advantage.
- **DTC advertising promotes the medicalisation of normal life**. The most heavily advertised drugs are for long-term use by large target audiences, often for mild conditions and 'lifestyle' problems that may not need drug therapy.



### Unnecessary Medicalisation

Why shouldn't normal New Yorkers feel anxious two months after the attack on the World Trade Centre, when this ad for paroxetine (Paxil) ran in the *New York Times Magazine*?

"Talk to your doctor about non-habit forming Paxil today," says the ad. The fine print on the back tells another story: discontinuation reactions include depression, somnolence, agitation, tremor, nausea, diarrhea, etc. Withdrawal reactions such as these signal a potential risk of drug dependence.

### Why is prescription drug advertising currently forbidden?

Compared with medicines that can be bought over-the-counter (OTC), prescription-only products are generally used to treat more serious diseases, have greater toxicity, and a less well-understood profile of risks and benefits. Prescription-only medicines cannot be bought and sold freely. The aim of laws restricting companies' marketing and advertising rights is health protection.

As prescription drugs often treat serious diseases, restrictions on advertising also take account of the extra vulnerability of people who are seriously ill. Someone in pain, who has been diagnosed with a debilitating illness, or who is caring for an ill family member is vulnerable in a way that is different from someone who is going shopping for a new car or a loaf of bread.

The current legislation reflects both rationales. The Food & Drugs Act prohibits all advertising of prescription-only medicines to the public, with the exception of price advertising, introduced in a 1978 amendment, Section C.01.044, which states that an advertiser, "shall not make any representation other than with respect to the brand name, proper name, common name, price and quantity of the drug." Section 3 prohibits all advertisements of preventatives, treatments or cures for a specified list of serious diseases (Schedule A diseases).

### What changes are being proposed?

Health Canada is proposing introduction of DTC advertising of prescription drugs, advertising of products to the public to prevent or treat serious diseases, and limits to its own responsibility for regulation of pharmaceutical advertising. In each case various options are presented in the discussion papers on these changes, including maintaining the status quo, but only deregulatory options are backed with detailed supporting arguments.

The detailed DTC advertising proposal includes some regulation of the content of ads and possible pre-clearance within the context of industry self-regulation. This is similar to New Zealand's regulatory system. In contrast, the US relies on direct government regulation. New Zealand ads contain much less risk information than US ads. The New Zealand approach has been criticized because of inadequate or absent risk information, exaggeration of benefits, slow and cumbersome procedures in response to complaints, and lack of sanctions or requirements for corrective information if the public is misinformed. (Coney, 2002)

If this system is worth emulating, why are the New Zealand Medical Association, college of family physicians, nurses' association, consumer association, women's health groups and others currently campaigning for a ban on DTC advertising? Why has the New Zealand Ministry of Health announced that it will soon harmonize its pharmaceutical advertising regulations with Australia – the first step towards a ban on DTC advertising? (Burton 2004)

Secondly, Health Canada is proposing either to severely restrict or remove the list of serious diseases for which preventatives, treatments or cures may not be advertised to the public. These diseases include cancer, heart, liver and kidney diseases, mental illnesses, diabetes, asthma, arthritis and many other diseases. This deletion would pave the way for across-the-board advertising targeting patients with serious illnesses. Although this part of the Act covers many products, not only prescription-only drugs, it acts as a legal barrier to DTC advertising, since most prescription drugs treat diseases that are listed in Schedule A.

A third proposed change involves the requirements for manufacturers to advertise truthfully. Under the Food & Drugs Act, manufacturers may not advertise a drug, "in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character, value, quantity, composition, merit or safety." (Section 9) Health Canada is proposing to limit its jurisdiction to *health claims* only, leaving other types of claims to the Competition Act. Thus if a manufacturer made false claims about the characteristics of a prescription or over-the-counter drug or a medical device, Health Canada would no longer be responsible to intervene.


We already have a problem with enforcement of the law. These changes would make it much harder to prevent manufacturers from providing false information about prescription drugs and other health treatments to the public. Will the public be exposed to false and misleading information for weeks or months while the legality of an ad is discussed by two different government departments, one responsible for health claims, the other for product claims?

### Is the current law being adequately enforced?

No. People are often surprised to hear that prescription drug advertising is illegal in Canada when we have TV ads for Viagra and billboards such as the one below. These are prescription drug ads. They are aimed at the public. They are not restricted to 'name, price and quantity' but include advertising images and text. They are inconsistent with both the public health aims of the restrictions on prescription drug advertising within the Food & Drugs Act and the wording in the Act.

Statements from Health Canada that a manufacturer may advertise the name of a drug, but not its indication (approved use), or the indication but not the name, are consistent neither with the wording nor the spirit of the Act. A Viagra ad with men jumping up and down to 'We are the champions' does nothing to promote rational drug use or public health. The drug is presented as a magic solution that works 100% of the time, and sexual problems as mainly being physical, not emotional or relational. There is not the slightest hint that this drug has side effects, in some cases serious.

Given the precedent of this liberal interpretation of the law, the federal government should introduce clarifying wording into the 1978 amendment (C.01.044), similar to those



Is this ad a posting of 'name, price and quantity'? Health Canada took no regulatory action in spite of complaints, apparently judging this ad to be legal under the 1978 price advertising clause.

Diane-35 (cyproterone and estradiol), is only approved in Canada to treat women with severe acne that is unresponsive to other treatments. Health Canada has sent out safety advisories about Diane-35 because of higher risks of potentially fatal blood clots than with other similar hormonal

drugs. As of January 2004, Diane-35 was named as the suspected cause in six deaths in Canada.

recommended for price advertising in Australia. (Galbally 2001) This includes limiting maximum print size, explicitly prohibiting illustrations, limiting such ads to suppliers (not manufacturers), joint listings of competing products and prices, and prohibiting radio and television ads.

### What rationale is presented for the proposed legislative changes?

One rationale is that current legislative restrictions predated the development of the television and the Internet and "are not well adapted to modern reality", in other words that Canadians are already exposed to cross-border and Internet advertising. In some cases, such as television stations near the Canadian border, this exposure is unavoidable. In other cases, such as magazines sold in Canada, cable programming aimed at a Canadian audience, or 'reminder' ads on television or billboards, it is a question of enforcement. Why is Health Canada allowing these ads to run, when they are prohibited on public health grounds?

A second rationale confuses consumer drug information with advertising. For example, 'tool 2' in the section of the proposal on direct-to-consumer advertising is about 'dissemination of consumer health product information', not about advertising. (Health Canada, 2003)

The current law does not limit the public's access to drug information; it prohibits *advertising*. Many organizations currently provide drug information to the public. Access to information is often inadequate, but this results from policy decisions not to prioritize patient information, rather than legal barriers.

Spending on DTC advertising has grown exponentially in the US within the last decade, from \$55 million in 1991 to \$2.7 billion in 2001. If DTC advertising did not stimulate sales, companies would not be spending more and more each year on this marketing strategy.

### Top 50 DTC advertised drugs responsible for large cost increases

- In 2000 over 95% of DTC advertising spending was on 50 drugs;
- These 50 drugs had combined retail sales of \$41.3 billion.
- This was nearly one third of total US retail prescription drug spending in 2000;
- These 50 drugs were responsible for **\$9.94 billion** of the **\$20.8 billion** increase in US retail prescription drug spending from 1999 to 2000, or 47.8% of this increase

(Findlay, 2001)

## The bottom line: why does the industry want legislative change?

A US market research firm, PERQ/CHI analyzed the returns on investments for print and television DTC ads in 1999, based on spending and sales data supplied by 25 major manufacturers. On each dollar invested in DTC advertising, the average return was \$1.69 for TV ads alone; \$2.51 for magazine advertising, and \$2.11 for campaigns involving a mix of print and TV ads. (PERQ/CHI, 1999) These are impressive returns – but they also mean impossible costs for public and private drug plans.

*“Aggressive direct-to-patient marketing by pharmaceutical companies, high prices for new drugs are making prescription drugs one of the major costs of health care. This issue is not being given the attention it deserves. It’s time to put science ahead of marketing.”*

**- British Columbia Government News Release. Victoria, B.C., Canada May 24, 2000, Premier Ujjal Dosanjh**

## Can the public find out what drugs are available from DTC advertising?

DTC advertising does not provide an overview of available treatments. Very few drugs are advertised to the public. In the US, over 40% of spending each year goes towards just 10 products. These are mainly new, expensive drugs for chronic or intermittent long-term use by large numbers of people. They exclude off-patent drugs even if these are superior first-line treatments, such as diuretics for uncomplicated high blood pressure. The decision to advertise a drug is a marketing decision, not a public health decision. Sales revenues for the top 10 drugs exceeded US \$16 billion in 2000.

### Products with Top DTC Advertising Budgets in 2000

Drug	Condition	DTC Spending Millions US\$	Sales Millions US\$
Vioxx (rofecoxib)	Arthritis	\$160.8	\$1,518.0
Prilosec (omeprazole)	Ulcer/Reflux	\$107.5	\$4,102.2
Claritin (loratadine)	Allergy	\$99.7	\$2,035.4
Paxil (paroxetine)	Anxiety/Depression	\$91.8	\$1,808.0
Zocor (simvastatin)	High cholesterol	\$91.2	\$2,207.0
Viagra (sildenafil)	Impotence	\$89.5	\$ 809.4
Celebrex (celecoxib)	Arthritis	\$78.3	\$2,015.5
Flonase (fluticasone)	Allergy	\$73.5	\$ 618.7
Allegra (fexofenadine)	Allergy	\$67.0	\$1,120.4
Meridia (sibutramine)	Obesity	\$65.0	\$ 113.2
<b>Total</b>		<b>\$924.3</b>	<b>\$16,347.8</b>

Source: Findlay, 2001

## DTC advertising: an accurate information source?

DTC ads are commonly found to violate US law because they contain inaccurate and misleading information. The US Food and Drug Administration (FDA) directly regulates drug promotion. The FDA sent out 92 notices to companies about regulatory violations between August 1997 and the end of 2001. (Heinrich, 2002) Repeat violations were common; including 11 letters to Schering-Plough on loratadine (Claritin); 14 to GSK on fluticasone (Flovent and Flonase) and 4 to Pfizer on atorvastatin (Lipitor).

In 1998, more than half of products advertised on US TV violated regulatory standards. (Koerner, 1999) The most common reasons were exaggeration of benefits and minimization of risks.

New Zealand depends on industry self-regulation, but in the most recent spot check (Pratt, 2000), the Ministry of Health found that five of six voluntarily submitted TV ads and a fourth of print ads violated the Medicines Act. This was in spite of voluntary pre-screening. In nearly all cases risk information was absent, incomplete or illegible.

Steven Woloshin and colleagues (2001) examined the content of DTC ads in 10 consumer magazines published in 1998 and 1999. Nearly 9 out of 10 ads “described the benefit of a medication in vague, qualitative terms” and did not provide any evidence to support claims; one-quarter used terms such as ‘proven relief, proven effective or clinically proven’; nearly one-fifth cited widespread use as a claim of benefit; and one eighth used personal testimonials.

Researchers in California looked at the educational content of US magazine ads published over a 10 year period, 1989-1998, based on whether the ad mentioned key pieces of information consumers need to know. (Bell et al, 2000) They found the educational value to be minimal:

- 91% did not say the likelihood of treatment success;
- 76% made no mention of other helpful activities, like exercise or diet;
- 73% did not mention any causes or risk factors for the treated condition;
- 71% made no mention of any other possible treatments;
- 64% failed to explain how the drug works.

## Does DTCA improve ‘patient choice’ and empowerment?

### Diabetes: blurring the distinction between life-threatening and life-saving

Rezulin (troglitazone) is a diabetes drug, banned in the UK in 1997 because of severe liver toxicity. Rezulin was advertised to the US public for over two years after the UK ban. It was eventually removed from the market in 2000. By that time it had been named as the suspected cause of nearly 400 deaths, 63 from liver failure. (Willman, 2000) US DTC ads for Rezulin stressed its widespread use: “more than 1,000,000 people have begun using Rezulin to help manage diabetes.” (Woloshin, 2001) These ads made no mention of the UK market withdrawal.

Two new drugs in the same class, Avandia (rosiglitazone) and Actos (pioglitazone) are currently on the US market, and are being advertised to the US public. Health authorities have issued warnings that both drugs can cause fluid retention leading to heart failure.

Any prescription drug may be advertised to the public in the US, even if it is similar to a drug withdrawn for safety reasons or has been associated with serious risks.

These new diabetes drugs have not been shown to save lives. They simply have not been tested for long enough in large enough groups of patients. They were approved for marketing on the basis of their ability to control blood glucose. This effect may or may not translate into long-term health benefits as compared to other drug and non-drug approaches. To quote an independent assessment: “*In patients with type 2 diabetes rosiglitazone improves some surrogate markers and worsens others. Long-term trials are required to know whether this class of drugs reduces morbidity and mortality outcomes.*” (Therapeutics Initiative, 2000)

### AIDS: Unrealistic Expectations of Treatment Success Linked to Risk-taking Behaviours

“*Direct-to-consumer advertising may be influencing trends of increasing sexual risk behavior and subsequent STDs including new HIV infections among MSM in San Francisco. Strategies to reduce the possible harmful effects of HIV drug advertising are needed.*” – Jim Klausner, San Francisco Department of Public Health

The San Francisco Department of Health warned in early 2001 that it was considering banning DTCA for AIDS drugs within the city limits. A survey of 262 male patients in San Francisco’s STD clinics had shown that young men were less likely to practice safe sex because the unrealistic images in DTC ads for AIDS drugs made it seem like AIDS

“... You present the statement “Avandia is not indicated for use with insulin” in the audio portion of your ‘Real Stories’ broadcast advertisement simultaneously with the super “Avandia- Help use the natural insulin in you.” This presentation minimizes the communication of the risk of the **Bolded Warning** by presenting consumers with conflicting messages about the use of Avandia and insulin... In addition your broadcast advertisement is misleading because you fail to present the precaution ...concerning weight gain caused by Avandia... Moreover, your print advertisement is misleading because the risk information is presented under the header “Strengthen your body’s own ability to help control blood sugar.” This presentation... minimizes the risks associated with Avandia treatment.”

#### US FDA letter to GSK, June 2001

“The 60-second ‘full-product’ TV advertisement is misleading because the totality of the images, the music and the audio statements that you present overstate the efficacy of Celebrex... [they] collectively suggest that Celebrex is more effective than has been demonstrated by substantial evidence.”

#### - US FDA letter to Searle, Nov 2000

“The graphics of the advertisement show a frustrated woman trying to pull her shopping cart out of its inter-locked lineup in front of a store. The concurrent audio states “Think it’s PMS? It could be PMDD.” The imagery and audio presentation of the advertisement never completely define or accurately illustrate premenstrual dysphoric disorder (PMDD) and there is no clear distinction between premenstrual syndrome (PMS) and PMDD communicated. Consequently, the overall message broadens the indication and trivializes the seriousness of PMDD...”

#### - US FDA letter to Lilly, Nov 2000

“I recently sat in on a focus group sponsored by a drug advertiser... The group remarks were mostly - how can you make statements like this since they wanted to show amazing benefits while downplaying any possible side effects. In the end it was a pure advertising show and all we disliked was overlooked. The ads run now and probably increased sales at the expense of doctors being pressured by regular patients for a drug they really do not need. Needless to say I support more stringent rules in this area.”

- John Madura, letter to British Medical Journal, Oct 19, 2001 [www.bmj.com/cgi/eletters/323/7318/889#EL1](http://www.bmj.com/cgi/eletters/323/7318/889#EL1)

could be effectively controlled. Some ads showed vigorous men climbing mountains. This is nothing like the reality of life on triple therapy. (Klausner and Kim, 2001)

Gay men with higher DTC advertising exposure were more likely to have engaged in unprotected sex with an HIV positive or unknown partner within the last month (27% vs. 16%) and were more likely to believe that triple therapy (HAART) had made HIV infection a less serious disease (25% vs. 17%).

The most important public health message for AIDS is prevention. Unrealistic advertising campaigns for AIDS drugs have interfered with that message in the US. Are there any guarantees that the same companies will behave more responsibly in Canada?



Climbing mountains, flexing muscles and throwing a javelin: unrealistic images of the reality of antiretroviral therapy.



### Mistaken Impressions: ad for an asthma drug, Singulair (montelukast)

The US Kaiser Family Foundation published a study on consumer responses to three television DTC ads in November 2001. One of the ads was for an asthma drug, Singulair (montelukast).

Singulair is one of two new oral asthma drugs in a class called leukotriene antagonists. Both were among the top

50 drugs advertised to the US public in 2000. Independent assessments have judged their place in the treatment of asthma to be limited. A 1999 drug bulletin states: "Average clinical effects are small and would unlikely be detectable by individual patients... [These drugs] cause average clinical benefits that are less than low-dose inhaled glucocorticoids." (Therapeutics Initiative, 1999)

The Kaiser Foundation study randomly assigned participants to view different ads, then compared knowledge between viewers and non-viewers. They found that more viewers of the Singulair ad knew that there were pills people could take to prevent or limit asthma attacks (71% vs. 36%). However, more Singulair ad viewers came away misinformed about what these pills do: 25% thought they could take a pill rather than an inhaler during an asthma attack versus 13% of non-viewers. This is dangerous misinformation, as it could delay effective treatment during a potentially life-threatening situation.

The ad says that Singulair doesn't work during an acute attack. However, this voice-over is accompanied by different text on screen and viewers may be distracted. The main emotive message is one of effective relief. Nowhere does the ad even hint that effectiveness is mild or inferior to inhaled steroids, which are also used for prevention. The US FDA allowed Merck to run this ad. Health Canada might similarly allow it. The information it contains is not false. However, the lack of information on relative efficacy is misleading.

In New Zealand, Merck's ad campaign for Singulair included a promotional offer of one month's free medication. (MacKinven, 1999) Nearly 20% of New Zealand's GPs prescribed the drug during its first two weeks on the market. The free promotional offer was criticized as creating an unnecessary strain on patients, since Singulair is expensive and is intended for long-term use.

### Do DTC ads lead to better health or health care services?

Pharmaceutical industry representatives claim that advertising improves communication between doctors and patients, that it will help untreated patients receive needed care at an earlier date, and that it improves compliance. (Holmer, 1999)

There is no evidence that DTC advertising improves doctor/patient relationships, and surveys of US doctors indicate that opinions are largely negative. (Lipsky, 1997; Time Magazine, 1998).

A study in doctors' offices in Vancouver, B.C., and Sacramento, California, looked at how often patients came in and

asked for prescriptions for advertised drugs, in settings with and without legal DTCA. (Mintzes et al. 2003) Patients in Sacramento were twice as likely to request an advertised drug, but in both cities three-quarters of the patients who asked for an advertised drug left the office with a prescription for that brand. Doctors were much more likely to be ambivalent about these prescriptions, judging half to be 'possible' or 'unlikely' choices for other similar patients, rather than 'very likely' choices. In contrast, they only judged 1 in 8 prescriptions not requested by patients to be possible or unlikely choices for other patients.

There is no evidence that exposure to DTC advertising can lead to better health, fewer hospitalizations or lower mortality. The industry claims that patients will see the ads, recognize their symptoms and get earlier treatment and therefore avoid more serious disease. However, there is no research evidence to back this claim. Some market research studies show that ad campaigns increase the number of doctor visits for advertised conditions, but they don't distinguish between people who needed medical care and people who did not have a medical problem and were therefore unlikely to benefit. Ad campaigns cast a wide net in order to maximize sales, often suggesting that common symptoms are signs of serious problems, as in the case of this ad for an Alzheimer's drug. This approach is unlikely to attract only those in need of care.



The effect of DTC advertising on compliance has not been adequately tested. In two surveys by *Prevention Magazine*, between 5% and 8% of respondents said that seeing ads made them more likely to take their medicines. (Prevention, 1998, 1999) Most users of advertised medicines said the ads did not remind them to take the drug. This survey is frequently cited

as evidence of improved compliance although it did not measure behaviour change and failed to mention what types of drugs the respondents were using. If they were symptomatic treatments such as allergy drugs or painkillers, improved compliance is of no health benefit and in some cases can cause serious harm. (Herxheimer, 1998)

Patients with chronic diseases such as AIDS or diabetes are often well informed about their illnesses. For such patients, the key role of ads is to stimulate a switch to newer, more

expensive drugs. The US experience shows that this can cause harm: Rezulin was an unnecessarily harmful new drug for diabetes; the leukotriene antagonists for asthma have a limited role in asthma therapy because of unimpressive efficacy; and ads for new AIDS drugs appear to have convinced some younger gay men not to worry about disease prevention.

## Recommendations

### 1. Above all, do no harm

Given the lack of evidence of benefit and considerable evidence of harm from the US experience, prescription drug advertising should not be introduced in Canada. Most prescription drugs treat serious illnesses for which glossy advertising campaigns are inappropriate and potentially dangerous.

Unless there is clear evidence of lack of harm and of health benefits, the prohibition against direct-to-consumer advertising of prescription drugs should be maintained.

### 2. Maintain coverage of essential medicines

*"Access to health care is a right enshrined in the European Union's Charter of Fundamental Rights and an essential element of human dignity. It must therefore be guaranteed for all."* - European Commission, December 2001

Prescription drug advertising threatens universal health care coverage by pushing drug spending out of control. Annual increases in pharmaceutical costs similar to the US \$10 billion (15%) increase in a single year from sales of DTC advertised drugs would make provincial drug plans unsustainable. Most of these drugs provide little to no advantage compared to existing alternatives. Most are more expensive.

### 3. Make shared informed health care choices a reality

Patients and the public need independent, comparative information on the pros and cons of all drug and non-drug treatments and the option not to treat. This type of information does not require a change to advertising legislation. It cannot be produced by pharmaceutical companies, which have a vested interest in selling a specific product. However, if informed choice in health care decisions is to become a reality, independent information needs to become an integrated part of Canada's health care system.

The key issue from a public health perspective is not how to reduce the protection offered by prescription-only status, but how to ensure that the public, throughout Canada, has access to comprehensive, unbiased and reliable medicines information

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Health Action International (HAI) is an informal network of some 150 consumer, health, development action and other public interest groups involved in health and pharmaceutical issues in more than 70 countries. HAI believes that all drugs marketed should meet real medical needs, have therapeutic advantages, be acceptably safe and offer value for money. website: <http://www.haiweb.org>.

The Canadian Health Coalition is a non-governmental health advocacy organization dedicated to preserving and improving not-for-profit health care and creating better conditions for good health. Website: <http://www.medicare.ca>.

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