Protecting Our Health:

New Debates

DES Action Canada in collaboration with
the *Working Group on Women and Health Protection*

Direct-to-Consumer Prescription Drug Advertising:

When Public Health is No Longer a Priority

In Canada, as in the vast majority of industrialised nations, it is illegal to advertise prescription drugs directly to consumers. Since 1998, Health Canada has been working on an overhaul of federal health-protection legislation, including the Food and Drugs Act. One of the proposed changes under discussion is to allow direct-to-consumer advertising of prescription drugs (DTCA).

There has been very little public discussion of what kinds of effects this policy change might have on public health, health care costs, or specifically on women. This brochure raises key concerns, discusses the experience with DTCA thus far, and makes policy recommendations that promote women's health and equality.

- The United States and New Zealand are the only countries where it is legal to advertise prescription drugs to consumers. DTCA is banned in most industrialised countries as a public safety measure linked to prescription-only status.
- Canadian law prohibits advertising of prescription drugs directly to consumers but Health Canada is not adequately enforcing the law.
- The Canadian Medical Association, the Canadian Pharmacists Association,the Consumers'Association of Canada and many other health organisations oppose the legalisation of prescription drug advertising aimed at consumers.

Why Prohibit Direct-to-Consumer Advertising of Prescription Drugs?

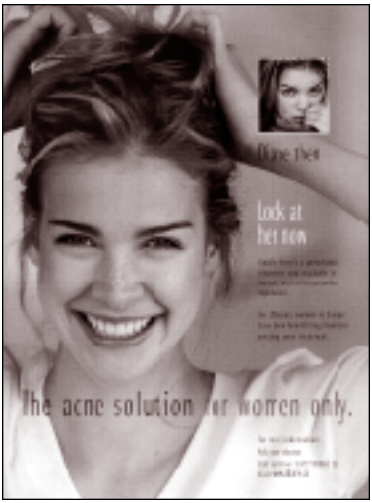
- Advertising drives up prescription drug costs.
- Advertising does not provide the impartial, objective information consumers need to make informed health choices. Its main goal is to increase product sales.
- Prescription drugs are not like other consumer goods. Even when used properly, they can cause serious harmful effects, sometimes even death.
- A sick person is not like someone shopping for a new perfume. People are vulnerable when they are ill and often have to make extremely difficult treatment choices.
- Companies almost always advertise their newest products to gain market share and recoup development costs. New drugs are not necessarily any safer or more effective, but are usually costlier. Often little is known about rare or long-term risks.
- There is no evidence that advertising helps patients to make better choices about prescription drug use or that public health will improve as a result.
- Doctors often rely heavily on manufacturers for information about drugs, rather than independent information sources, which are often less easily accessible. Studies show that the doctors most influenced by pharmaceutical promotion tend to prescribe less appropriately.

The aim of advertising is to increase product sales.The massive growth in spending on direct-to-consumer advertising in the U.S., from US $55 million in 1991 to $1.8 billion in 1999,and an estimated $2.6 billion in 2000 indicates that this form of advertising is paying off.

In the U.S., prescription drug spending increased from US $50.6 billion in 1993 to $93.4 billion in 1998, an 84% increase over a five-year period. Four categories of drugs accounted for 30.8% of this increase: oral antihistamines used to treat allergy, antidepressants,cholesterol-lowering drugs and ulcer treatments. These categories include seven of the ten drugs most heavily advertised to the public in 1998.That means that direct-to-consumer advertising could have added more than $13 billion to the US drug bill in 1998. In 1999, two thirds of the increase in spending on prescription drugs in the US was for 25 drugs with the most intensive DTC advertising campaigns.

Illegal and Harms Women

Montreal, fall 1999. Berlex runs ad campaign for its acne treatment, Diane-35.



Source: Chatelaine, March 2000.

The ad implies that Diane-35 is an easy, risk-free solution to acne for women.

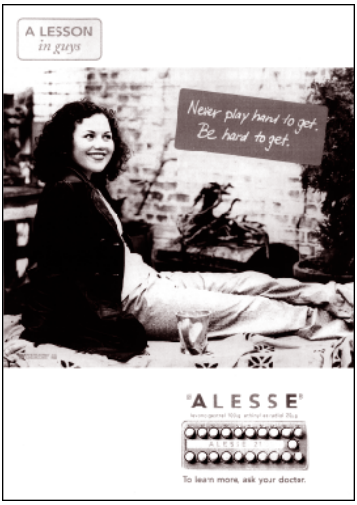
- The hormonal drug Diane-35 has been approved in Canada only for the treatment of severe acne when other options have been tried and have failed. It is a second-line treatment.
- It is associated with serious risks of liver toxicity. There is also evidence that it may be linked to a higher risk of potentially fatal blood clots than other similar hormonal products.
- According to information from the World Health Organization, several countries have imposed restrictions on the use of Diane-35 because of these hazards. It used to be sold as a birth control pill in Europe; it is now no longer approved for this use. Why is a second-line drug with potentially serious side effects being advertised in bus shelters?

Pharmaceutical companies are breaking Canadian Law

Since 1997, when the US relaxed its laws on TV and radio ads, Canadians have been exposed to a massive amount of US DTC advertising. This is due to non-enforcement of the Food and Drugs Act by Health Canada; cable TV providers serving Canadian audiences could be asked to replace ads that are illegal in Canada.

Since autumn 1999, a number of prescription drugs such as Zyban or Propecia have been advertised directly to consumers in major Canadian cities. In addition to Diane-35, described above, the oral contraceptive Alesse has also been widely advertised (see below).

With these ads, pharmaceutical companies are breaking Canada's Food and Drugs Act. Health Canada is not taking the necessary steps to enforce the law. Despite official complaints and pressure from over 20 consumer groups demanding that the Minister enforce the law, the advertising continues.



Source: Healthy Woman, First Issue, October – November 2000.

Alesse: Young women are being targeted by an emotive advertising campaign that cultivates a "cool" image.

This advertising campaign uses images of "cool" with-it young women to sell a product. Several variations of this ad use different advertising text but similar graphics and images. The text all starts with "a lesson in", to sound like the product name, Alesse. For example, the text in one of the ads is: "A lesson in first impressions. Always leave something to the imagination. Be mysterious". This lesson certainly will stimulate sales of Alesse, but recommending an approach to new sexual relationships that would fail to protect young people from sexually transmitted diseases, including AIDS, is highly questionable in this day and age.

Health Canada is turning a blind eye to illegal advertising by pharmaceutical companies

Since 1998, Health Canada has been discussing proposals to change national health protection legislation. The Food and Drugs Act would be abolished and replaced with a new federal Health Protection Act. One of the changes being proposed is the introduction of some form of direct-to-consumer prescription drug advertising.

In the meantime, without any public or parliamentary debate, the government has stopped enforcing the law and now says that certain forms of direct-to-consumer advertising of prescription drugs are legal in Canada: reminder ads and help-seeking ads. In reminder ads the name of the prescription drug is mentioned but not the disease or condition for wich it is prescribed. For example, the ad would read: "Diane-35: Ask Your Doctor". In help-seeking ads, a disease or condition is discussed but no specific prescription drug. For example, such an ad would talk about birth control without mentioning the name Alesse.

The assertion that these forms of DTCA are legal relies on two key points:

1) The confusion between educational materials and advertising, as if advertising provided balanced, objective information;

2) A 1978 amendment to the Food and Drugs Act passed to allow pharmacists to display their prices so consumers could benefit from competitive pricing.

What does the law say?

The Food and Drugs Act contains blanket prohibitions against advertising to the public of products that prevent and treat specific serious diseases, as well as advertising of prescription drugs. The sole exception to the latter restriction is the postings of a drug's name, price and quantity. The Act makes it clear that this is a clearly defined, limited exception:

Section C.01.044: **"Where a person advertises to the general public a Schedule F 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."**

A 1999 Health Canada Discussion Document clarifies that: "This amendment was meant to accommodate price comparisons for consumers."

The general prohibition of direct-to-consumer advertising is explicitly linked to the protection offered by prescription-only status.

"As the intervention of a medical practitioner is required in the supply of these drugs to the general public, advertising to the general public with respect to these drugs is restricted to name, price and quantity by Section C.0.1.44." – Health Canada 1999.

Nothing in the Food and Drugs Act or the accompanying regulations states that either reminder advertisements or help-seeking advertisements are legal. The Act broadly defines advertising as any representation by any means whatever for the purpose of promoting directly or indirectly the sale of any food, drug or cosmetic device.

A "reminder ad" or a "help-seeking ad" that aim to promote the sale of a medicine are clearly included within this definition. Manufacturers only pay for advertising space to say "Zyban: Ask Your Doctor" or to suggest that you "ask your doctor about weight loss options that are available now", if they have a product for sale. A drug company will never tell you "ask your community centre about gym equipment that is available now" although the evidence in favour of exercise vastly overshadows the questionable benefits of diet drugs.

The World Health Organization has developed a set of criteria for the ethical marketing of pharmaceuticals. These guidelines spell out clearly that advertising must not be disguised as an educational activity. Canada expressed its support for these guidelines in successive World Health Assemblies from 1988 to the present, and ratified resolutions calling on national governments to implement them. Is our government happy to support fine principles – if they are for someone else – but reluctant to implement them nationally?

Health Canada is not adequately enforcing the Food and Drugs Act. This has already weakened the public health protection offered by prescription-only status. If the government wants to change the law, they should bring forward new legislation in Parliament. They shouldn't simply stop enforcing. This kind of change needs to be subjected to full public and parliamentary debate, not be made behind the scenes through a reinterpretation of the law that serves industry's interests only.

Advertising = Education of the U.S. Public?
A Misleading Kind of Education

Thirty-three medicines were advertised on US TV between late 1997, when the US FDA relaxed its regulations and made it easier for companies to advertise on TV, and the end of 1998. The ads for seventeen of these 33 drugs — more than 50% — were found to violate FDA regulations, most commonly by downplaying risks. Some ads also exaggerated benefits and implied that the products could be used to treat a wider range of conditions than the government approved them for.

Pravachol: Bristol-Myers Squibb used women athletes in advertisements promoting the use of its drug Pravachol, which is approved for lowering cholesterol, to reduce the risk of heart attacks. The FDA judged this to be misleading because Pravachol has never been shown to protect women against heart attacks.

Sarafem: The FDA judged that a television ad for Sarafem (fluoxetine) showing a woman angrily pushing a shopping cart in a crowded supermarket was illegal because it hinted that any woman with pre-menstrual mood swings could benefit by using this antidepressant. Sarafem is the same product as Prozac sold under a different name. It has been approved for use for pre-menstrual dysphoric disorder, a more serious mood disorder, not for pre-menstrual syndrome.

Premarin: The FDA objected to ads for Premarin, a hormone treatment for menopause, because Wyeth-Ayerst claimed vague, unspecified health benefits when there is no good evidence of any benefit from that drug other than reducing menopausal symptoms.

Newer is Not Necessarily Better

A company doesn't have to show that a new drug is any better than existing treatments to get permission to market it in Canada. It generally only needs to

The Canadian Situation: Looking at the Pitfalls of Direct-to-Doctor Drug Promotion

Promotion directed at physicians in Canada is often misleading. Risks are often minimised, and benefits overstated. Furthermore, very few studies on new drugs are carried out by independent organizations. Most are funded by manufacturers. Studies have shown the research funded by drug companies is often biased in favour of the company's drug.

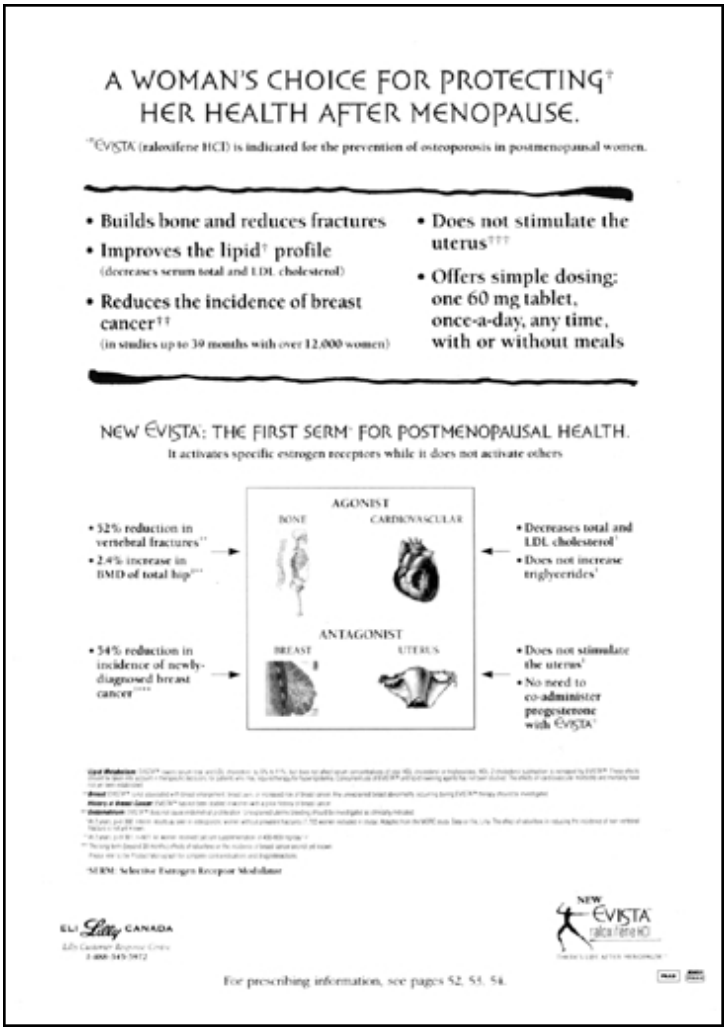
In Canada, most drug promotion is regulated by the industry itself. Rx&D, the brand-name pharmaceutical industry association, regulates its own promotional activities aimed at doctors. These activities include the visits of sales reprensentatives to doctors' offices, donations of free drug samples, and organization of meetings and conferences, among others. This "regulation" involves no active monitoring, no requirements that companies correct misinformation and fines that range from $1,000 to a maximum of $15,000 in a year – peanuts compared to the profits to be gained by misleading promotion.

Published ads in medical journals and other forms of print advertising addressed to the medical community are regulated by the Pharmaceutical Advertising Advisory Board (PAAB), a semi-autonomous organization formed by the drug and advertising industries along with representatives of health professional associations and consumers. PAAB's standards are much too low. They allow companies to use large headlines to loudly proclaim potential benefits in the main colorful portion of the ad, and to confine risk information to footnotes in tiny print or to prescribing information at the back of the medical journal. In May 2000, PAAB acknowledged this problem and asked companies to present more balanced benefit and risk information. Unfortunately, however, the requirements remain vague and do not specify a minimum type size or state that certain types of risk information must be included in the main part of the ad.

PAAB prescreens ads and responds to complaints. If a complaint is upheld and an ad is found to be misleading or inaccurate, most of the time the only action required is for the company to stop running the ad. The process often takes so long that the ad would have been replaced anyway. Usually, the company is not required to publish a correction to let doctors, pharmacists or other health professionals know the information in the ad was misleading or incorrect. PAAB publishes a quarterly newsletter describing complaints that have been upheld, but makes no effort to ensure that information goes out to those who have been duped. This inaction on the part of PAAB also stops doctors and pharmacists from finding out what is and is not acceptable practice under the PAAB code.

Studies of how appropriately doctors prescribe consistently show that those who rely more heavily on drug promotion as an information source prescribe less appropriately. Prescribing appropriateness is defined in these studies as prescribing a drug for a condition it is indicated to treat; prescribing the right dose; avoiding unnecessarily harmful drugs; and prescribing the least expensive of equivalent drugs.

An ad for Evista in Canadian medical journals: Eli Lilly pushes the limits of the law - and beyond



Source: The Canadian Nurse.

- The ad for Evista (raloxifene), a drug approved to prevent osteoporosis, was pre-screened and approved by PAAB although it promotes the drug for unapproved uses. A complaint was filed and PAAB eventually required Eli Lilly to withdraw the ad, five months later. No corrective information was published. The company has not been fined nor subject to any other sanctions. When it ran this ad in Canada, Eli Lilly had already been required to stop making similarly exaggerated advertising claims in the US.
- The drug has not been approved in Canada, or in any other country, to prevent breast cancer, protect against heart disease or relieve symptoms of menopause. It has been approved only to prevent osteoporosis (thinning of the bones).
- The information the ad provides on fracture prevention is extremely misleading. It refers only to symptomless vertebral collapse (also called spinal fractures) that were visible on X-ray. Vertebral collapse often causes no pain, disability or any other problems for the rest of a person's life.
- Although this drug is selling well because of women's fears of disability following serious fractures such as hip fractures, it has not been shown to prevent any type of non-spinal fracture. Hip fractures in elderly women can have serious long-term consequences including death. Evista did not lead to a significant reduction in any hip or other non-spinal fractures: 8.5% of women taking raloxifene had a non-spinal fracture compared to 9.3% of women on a placebo (sugar pill).
- Evista made only a small difference to painful vertebral collapse. Over a three year period, 0.8% (or **8 in 1000**) fewer women on Evista had back pain associated with vertebral collapse than women on placebo.
- The ad fails to mention that Evista can cause deep vein thrombosis. This is the formation of blood clots, usually in the leg, but which can also travel to the lungs and be fatal. In the three-year study on fractures mentioned above, women taking Evista were three times more as likely to develop deep-vein thrombosis: 1% of women taking Evista developed deep-vein thrombosis, compared with 0.3% of women on placebo. In other words an extra 0.7%, or **7 in 1000** women, developed deep vein thrombosis during this study because they took Evista. The difference was statistically significant, $p<.001$.
- The number of women helped by Evista was very similar to the number harmed by Evista.
- Additionally, women taking Evista were significantly more likely to experience hot flushes and leg cramps than women not taking the drug.
- The ad also fails to mention that in studies of both mice and rats, this drug caused cancer of the ovaries.

We Need a Law that Will Protect Health

Recommendations

1. Direct-to-consumer advertisements of prescription drugs should not be allowed, given the lack of evidence of health benefits and the serious potential for harm. The legislation should ban full advertising, which includes both the product's name and indications (approved reasons) for use. It should also ban advertising that clearly aims to stimulate sales of a specific product by either mentioning the drug's name but not its use or its use but not its name. It should also ban cross-border direct-to-consumer advertising.

2. The 1978 amendment allowing pharmacists to post comparative prices should be accompanied by explicit, rigorous criteria to ensure that it is used for this purpose, and not as a loophole to allow reminder advertisements. This could easily be done with a small amendment to the regulations in the Food and Drugs Act. An Australian committee reviewing their health protection legislation has suggested a number of useful criteria for price advertisements for prescription drugs. These included limits to the size of allowable font for brand names, joint listings of products from different manufacturers, and prohibitions of publication of any images or illustrations with the price comparisons, or of accompanying them with other promotional materials. The Australian recommendations also suggest that comparative price advertising should not be allowed on television or radio.

3. Regulation of drug promotion to doctors in Canada is a public responsibility and should not be left up to the industry. It should be carried out directly by Health Canada or by an independent body, at arm's length from both the pharmaceutical and advertising industries. Such a body should have the legislated authority to actively monitor and enforce compliance by imposing sanctions and corrective actions, with full procedures in place for public reporting and for transparency and accountability of decision making.

4. The principle on drug promotion included in section 9(1) of the Food and Drug Act is sound. It states: "No person shall label, package, treat, process, sell or advertise any drug in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its composition, merit or safety." This principle needs to be enforced, with active monitoring, effective sanctions and corrective actions for violations, and full public accountability in decision making.

5. Lay people need up-to-date, accurate, comprehensive and unbiased information on the pros and cons of all treatment options, both drug and non-drug, as well as the option not to treat, for the health conditions and illnesses they face. They need access to this information as a part of basic public health care services. To ensure lack of bias, information providers should not receive funding from product manufacturers or industry associations, unless it is provided through an independently administered blind trust.

6. Canada should implement legislation based on the World Health Organization Ethical Criteria, including provisions stating that promotion should be in keeping with national health policies and should not be designed so as to disguise its real nature, for example, as educational or scientific activities.
7. Given the problem of unnecessary medicalization faced by women, where a stage of life such as menopause is defined as a deficiency state or a disease risk needing drug treatment, and with the widespread overprescribing of psychotropic drugs to women, regulation of drug promotion should include representation by women's organizations and explicit attention to gender equity. Promotional messages for health professionals promoting further gender inequality, inappropriately targeting women for treatment, or fostering a disrespectful attitude towards women should be prohibited.

The aim of this booklet, jointly published by DES Action Canada and the Working Group on Women and Health Protection, is to counteract strong pressure by the pharmaceutical industry to convince our national government to legalize direct-to-consumer advertising of prescription drugs.

This is the second in a series of pamphlets examining new health protection issues. Health Canada is currently overhauling federal health-protection legislation, including the Food and Drugs Act. The interests of the pharmaceutical industry, the food industry and the chemical industry are clear and well understood by our representatives. The time has now come for citizens to make their voices heard and demand that Canadian legislation truly provide "health protection".

DES: The first synthetic estrogen was shown to be ineffective to prevent miscarriage, but was prescribed for this indication between 1941 and 1971 in North America and even longer in Europe.

- was prescribed to millions of women worldwide
- continued to be used in pregnancy nearly 20 years after it was found to be ineffective
- was sold and widely used in spite of good evidence from animal studies that it might cause cancer
- was found to cause cancer in young women, 30 years after it was first prescribed

DES (diethylstilbestrol) was one of Canada's worst drug disasters.

Between 200,000 and 400,000 pregnant women and their children were exposed to DES. DES was advertised for use in ALL PREGNANCIES with a suggestion that it would lead to "BIGGER AND STRONGER BABIES".

To obtain the bibliography of this brochure, contact

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Information on the following topics is also available: Monitoring of the risks of drugs after they are approved for marketing, Medical and non-medical approaches to disease prevention, Environmental estrogens.

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