External Working Group Report on

Section 3 and Schedule A

Minority Report

- Union des consommateurs

- Women and Health Protection

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Introduction

The External Working Group on Section 3 and Schedule A of the Food & Drugs Act was formed in February 2003 in response to one of the recommendations of the House of Commons Standing Committee on Health, asking that Health Canada:

> *"... conduct a study with the participation of representatives from consumer groups, the food, natural health products and pharmaceutical industries, and health practitioners to determine whether subsections 3(1) and (2) of the Food and Drugs Act or all of the diseases listed in Schedule A should be deleted*."

Commercial Interests

The Working Group includes representatives from the over-the-counter drug industry, the medical devices industry, the natural health products industry, the food industry, advertising and media. Additionally, patient groups and professional associations with financing from the prescription drug industry, over-the-counter drug industry and natural health products are represented on the Working Group.

It is legitimate for Health Canada to request advice on health policies from the regulated industries. However, such advice must be understood within the context of companies' fiduciary responsibility to their shareholders, and the responsibility of industry associations to uphold the interests of their member companies. Additionally, conflicts of interests may arise when a patient or health professional group has financialcop ties to an industry or company that produces health-related products, or when an organization's representatives have individual financial ties, for example as paid consultants or advisory board members.

Most of this committee's non-governmental members have financial ties to the industries that stand to gain from expanded health product advertising. If the aim of this committee is to address whether, from a public health perspective, changes to Schedule A are needed, then an advisory group should be composed of organizations and individuals with expertise in public health, and attention should be paid to avoiding all apparent and real conflicts of interests on such a committee.

This minority report is from two members of the Schedule A External Working Group from consumer organizations without financial ties to the pharmaceutical, health product, advertising or media industries: *Union des consommateurs* and *Women and Health Protection*.

Background

Why prohibit advertising of preventatives, treatments or cures for serious diseases?

The list of Schedule A diseases was introduced into law as a health protection measure, in order to protect the public against undue commercial influence at a time when they are most vulnerable due to ill health. People who are seriously ill, caring for an ill family member, or who fear future death and disability are vulnerable in a way that differs from someone who is facing a consumer product choice, such as buying a new car or an item of clothing.

Advertising is a poor mechanism to provide unbiased information related to the treatment of serious diseases. By definition, advertising aims to sell a product. It cannot provide the type of complete, accurate and unbiased information on pros and cons of all available treatment options that the public needs in order to participate in informed treatment or prevention choices.

Whether or not the original intent of the restrictions on advertising imposed by Schedule A was to prevent charlatans from selling ‘snake oil’ remedies to the public at a time when fewer regulatory controls were in place, when it comes to health claims in advertising, the aims underlying Schedule A restrictions remain as pertinent today. During the time since Schedule A was introduced, advertising techniques have become much more sophisticated than in the past, and are extremely subtle and effective.

The vulnerability of those seeking to prevent death and disability from serious disease was highlighted in a recent letter to the medical journal *The Lancet* by World Health Organization staff about an advertising campaign in France. The campaign, which featured a tagged toe of a corpse in the print version, and a man dying of a heart attack in the television commercial, has also been running in Canada during 2003.

The letter's author, Dr Jonathan Quick, Director of the Essential Drugs and Medicines Policy Division, and his staff, stated that this advertising campaign: "contained misleading statements and omissions likely to cause medically unjustifiable drug use or to give rise to undue risks."

The ads use fear of death to sell a product. They provide unrealistic expectations of the effectiveness of the recommended prevention strategy, since cholesterol testing and use of a cholesterol-lowering drug have never been shown to prevent deaths from heart attacks in those without previous heart disease. They also convey the impression that this strategy is the most effective way to prevent cardiac death, which may lead viewers to substitute this strategy for more effective interventions, such as quitting smoking, exercise and weight loss. The *Globe & Mail* featured a full-page version of this ad on November 22, 2003, and complaints to Advertising Standards Canada have thus far gone unheeded.

Similarly, in September 2003, a margarine producer promoted its product, Becel, as part of a 'healthy heart strategy', in a Canadian magazine, *Healthy Woman*, although the idea that eating margarine prevents heart disease has long been discredited.

Is the Canadian public currently protected against misleading advertising claims?

These examples point to a widespread problem of inadequate enforcement of the law prohibiting deception in advertisements for health products. Lack of enforcement leads to misleading and potentially hazardous messages about medical treatments reaching the Canadian public, without any mechanism in place to ensure swift removal of offending advertising campaigns or correction of misleading information. As described above, these violations include advertising of preventatives and treatments for Schedule A diseases.

The most recent review of the adequacy of enforcement of over-the-counter drug advertising regulations was carried out by Health Canada in 1993, and published in a 1994 report. Two-thirds of sampled magazine ads failed to comply with the law. 'Minor' violations included exaggerations of benefits and inadequate risk information, in other words misleading and inaccurate information about the products' characteristics and health effects; major violations were not defined. The 1993 review of broadcast advertisements only included scripts submitted for review, not full commercials that were heard and seen by the public. However, approximately one-third of these scripts failed to comply with regulatory requirements. These violations occurred while Health Canada was still

directly responsible for monitoring the promotion of OTC products and when it was pre-screening scripts for broadcast advertisements. Since then responsibility for OTC promotion has been turned over to Advertising Standards Canada.

No systematic evaluation of the adequacy of enforcement procedures has been carried out during the last 10 years. To assume that the public would be well protected, should current restrictions on advertising be lifted, appears to be based on a leap in faith rather than a careful assessment of available evidence.

A precautionary approach to health protection policy

We agree that the guiding principle in considering changes to Section 3 and Schedule A of the Act should be protection and promotion of public health. A further question concerns where the burden of proof should lie.

When a new health technology or drug is introduced onto the market, the burden of proof is on the manufacturer to provide systematic evidence to Health Canada to show that the product has the claimed effect, and is sufficiently safe; in other words that the product's potential benefit will outweigh potential harm. Similarly, the onus should be on those supporting removal or limitation of the scope of an existing health protection measure to show that such a move will lead to greater benefit than harm. When it comes to product-specific advertising of preventatives, treatments or cures for serious diseases, such evidence is sorely lacking.

The question is whether a precautionary approach should be applied to policy development on health-related advertising, or an approach giving greater priority to economic development over public health.

If promotion of a specific intervention is desired, as is the case for example for condoms and prevention of spread of sexually transmitted diseases, advertising campaigns may be used by public health authorities without any changes to Schedule A. It is also possible to make exemptions to Schedule A restrictions involving a specific type of product, such as condoms or sunscreens. Such exemptions already exist, and are preferable, on a case by case basis, to removal of serious diseases from Schedule A, given the importance of avoiding promotion of less effective prevention and treatment strategies, or broad promotion of interventions that are beneficial for patients at high risk, but will create greater harm than benefit in other population groups.

An example of the potential for problems is the use of aspirin by patients with previous heart attack and stroke, in order to prevent recurrences. This is a useful preventative measure. However, advertising of aspirin could lead to use in primary prevention in patients at lower risk or who mistakenly believe that they are at high risk. In such patient populations, risks of daily preventative aspirin therapy could easily outweigh benefits, leading to more hospitalizations and potentially more deaths from stomach bleeding.

As this example points out, non-prescription status does not necessarily imply that a product is risk free, especially when used inappropriately. Additionally, advertisements may lead to serious harm if they promote the substitution of less effective approaches to disease prevention or treatment, rather than the most effective available alternative.

There is a fundamental difference between limits on *advertising* of products for serious diseases and limits on the public's *access* to those products. Neither are limits on advertising synonymous with limits on the public's access to *information* on options for treatments and prevention of serious diseases. Limits on advertising are a means, rather, to ensure that the public obtains information about options for treatment and prevention of serious diseases from independent and unbiased information sources, including health care professionals, and not from emotive messages whose aim is to sell a product.

The distinction between advertising and labelling

Section 3 of the Food & Drugs Act refers mainly to restrictions on advertising of products used to prevent or treat listed diseases. However, it also includes restrictions on labelling.

If a product has been approved as a preventative, treatment or cure for a Schedule A diseases, and the pre-market approval process includes approval of product information, that information should be available to the public in a format similar to the 'Patient Product Monograph' that Health Canada is currently developing for prescription drugs.

For all products labelled for a Schedule A disease, this information should include at a minimum, in plain language:

- The approved indication
- Dosage and administration

- Contraindications
- Adverse effects [both those that occur most frequently, and the most serious potential adverse effects, organized in a readable and coherent manner]
- Interactions to avoid
- Symptoms to watch out for and what to do in case of specific symptoms or unforeseen adverse effects
- The Health Canada 1-800 number for reporting adverse effects
- A statement, in bold, indicating the need for ongoing assistance from a doctor or other health professional in the management or treatment of 'xx [Schedule A disease or condition]'

Provisions to introduce such labelling changes should include limits on font size [both minimum and maximum], a complete prohibition of accompanying images as well as advertising text and testimonials. As this is labelling information, media could also be limited for example to the product package and either print or web-based compendia of non-prescription health products (on a similar model to the CPS).

Labelling of a product associated with Schedule A diseases should only be allowed for products with pre-approved product information.

Relationship of Schedule A to direct-to-consumer advertising of prescription drugs

A separate provision in the Food & Drugs Act prohibits advertising of prescription-only drugs to the public, with the exception of advertisements that make no representation other than name, price and quantity. Additionally, Schedule A covers any product, and is thus not limited to products with prescription-only status. However, it acts as a second barrier to advertising of most prescription-only drugs to the public, given that most prescription drugs are used for prevention, treatment or cure of serious diseases. Thus, elimination of Schedule A may be seen as a *necessary* but not a *sufficient* legal change for the introduction of direct-to-consumer advertising of prescription-only drugs in Canada.

Many of the same concerns that have been raised about direct-to-consumer advertisements of prescription drugs (DTCA) are relevant to advertising of

non-prescription medicines to the public for prevention and treatment of serious diseases. These include for example:

- unnecessary medicalization of the population,
- the creation of unrealistic impressions of treatment success,
- ignoring key treatment information, particularly in relation to treatments that do not rely on marketed products
- interference with the doctor/patient relationship
- and presentation of an unbalanced picture of potential risks.

Currently, legal restrictions on non-prescription health product advertising are consistent with conditions for self-care, in that products are advertised for symptomatic treatment and for generally mild conditions. If Schedule A restrictions are eliminated, advertising of non-prescription products will focus on health conditions that normally require diagnosis and treatment by a health professional. There is a risk of creating an imbalance in the types of messages reaching the public about different classes of health products and treatment options indicated for the prevention and treatment of serious diseases. This is likely to create additional pressure from manufacturers of prescription-only drugs for legalization of DTCA. Additionally, prevention and treatment strategies that do not involve product sales (such as wearing protective clothing, quitting smoking, exercising, losing weight or reducing stress) will not receive the attention of product-specific strategies, even when they are the most effective options available.

Should the scope of a law be limited through redefinition of terms?

We have strong concerns about the short-term recommendation being put forward by the Working Group, as an example of an attempt to radically limit the scope of an existing law through administrative policy. Such an approach bypasses the need for full public and parliamentary debate, and is antithetical to a commitment to accountable, open and transparent government.

The following changes to the definition of terms in the law are being recommended:

1) Redefinition of prevention to mean 'absolute' or '100%' prevention. All other forms of prevention would be called 'risk reduction', which is not mentioned in the law, and therefore would lie outside the scope of the law.

   This recommendation is neither in keeping with the spirit of the current law, common understanding of the term prevention, nor the way that Section 3 has been interpreted during the last 50 years of the Food & Drugs Act's implementation. We question whether it would stand up to judicial review.

   No product currently available for prevention of any of the listed Schedule A diseases has the capacity to prevent the disease absolutely. Thus, under the recommendation being put forward by the Working Group, the prohibition on advertising of products for prevention would be eliminated through the redefinition of such activities as promotion of risk reduction.

2) Redefinition of 'treatment' to include only disease-modifying treatment, not symptomatic treatment. Although not as drastic as the redefinition for prevention recommended above, this is a recommendation to limit the scope of the law by redefining terms within it. Many treatments have both a symptomatic and a disease-modifying function, and in practice, this redefinition would create the need for a more complex approach to enforcement. Additionally, it is inconsistent with common understanding of the word 'treatment'. Under current law, advertisers may state that a drug provides symptomatic relief, and may specify the condition or disease if it is not covered by Schedule A (i.e. the majority of minor illnesses that are self-treated and do not generally require medical intervention to prevent serious complications.)

Recommendations

1. Enforcement

Under current law, there is a need for effective, adequately resourced, enforcement procedures, with active monitoring, adequate standards, correction of misinformation that reaches the public, and effective prevention of repeat violations. Additional public resources are needed. Enforcement should be

regularly evaluated, to ensure not only that the information in advertisements is consistent with approved product labelling, but that the message as understood by the public is consistent with a product's characteristics and potential health effects, both beneficial and harmful, including the proportion of people helped or harmed and the magnitude of effect.

2. Schedule A Diseases

Most of the listed Schedule A diseases are serious and require medical care, such as cancer, heart disease or kidney and liver disease. However, Schedule A also includes some historical anomalies. We recommend that the list be rationalized by applying an international disease classification system that is currently in use for diagnostic coding in medical care, and disease surveillance at a population level, such as ICD-10.

The following criteria should form the basis for current and future inclusion of diseases in Schedule A:

1. The condition or disease results in a serious risks to individual or public health, and/or generally requires diagnosis, treatment or management by a health professional
2. The disease is likely to spread without appropriate treatment
3. Emergency situations where self care is inappropriate
4. The severity of the disease limits the person's ability to make health decisions
5. The disease state is new and still under investigation
6. The disease or condition is one which renders individuals especially vulnerable to harm from unnecessary exposure to drugs and other health care products (for example risks of teratogenicity through pregnancy-related exposures, and specific risks to infants and children)

Criteria for inclusion of diseases in Schedule A, currently and in the future, should provide guidance to government. These should not be inflexible rules, but rather should allow the flexibility, should a future need arise on public health grounds, to limit advertising of health products to the public.

The members of the Working Group were asked to go through the list of diseases in Schedule A and recommend modifications based on a similar set of criteria. This exercise clarified for us the potential differences in interpretation of

such sets of criteria when they are applied to specific diseases or health conditions. We therefore strongly recommend that the criteria above be used broadly for guidance, with a key emphasis on health protection, and that the final decision for inclusion or exclusion of Schedule A diseases be left with a committee of independent experts in public health.

3. Ensure that provisions governing advertising and product labelling are separated within the law.

The current definition of advertising within the Food & Drugs Act is clear and broad enough to cover a range of activities including indirect as well as direct product promotion. We suggest that the 1996 Health Canada Guidance Document "The Distinction Between Advertising and Other Activities" be reviewed. In our opinion, this guidance document restricts the definition of advertising and has contributed to an inconsistent approach to enforcement of the law. We support labelling of products that is consistent with approved product information. Labelling standards for products that a person buys directly from a drugstore or a health food store should be as high as for prescription-only products.

Additionally, if the standards for evidence used to approve a specific product for a Schedule A disease are lower because of the product's classification (for instance not classified as a drug), this should be made clear to the consumer, in a prominent manner, on the label, including a description in plain language of the type of evidence provided.

4. Provide adequate resources for independent, unbiased information on all available options for disease prevention, treatment and cure, including information on Schedule A diseases.

This should be publicly financed, and should be produced only by individuals and organizations with no apparent or real conflicts of interests involving producers of health products or the media.

5. Fully accountable, transparent regulatory procedures are needed.

All laboratory, animal and clinical studies of safety and effectiveness of a product that have been submitted to Health Canada in order for a company to obtain market approval for a product used to prevent, treat or cure a Schedule A disease should be publicly available. Additionally, meetings of expert advisory committees discussing such product approvals should be conducted in public, and the rationales for regulatory decisions, should be made public.