NB: This document was developed by Legislative Renewal staff as a working document for internal purposes, with a focus on content rather than presentation. However, it is being made available to the public to provide background information.

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EXECUTIVE SUMMARY

Schedule A of the *Food and Drugs Act* lists a number of diseases and disorders for which treatments, preventatives or cure cannot be advertised to the general public. The reasons given to support this prohibition since its introduction into the Act in 1934 include: to prevent fraud; to prohibit the advertisement of treatments for conditions for which no treatment exists or which are not safe; and to encourage people to seek medical attention for serious conditions.

Schedule A has been criticized because of the lack of criteria to determine which ailments are to be included and because it restricts the dissemination of information on the products labels. On the other hand, Schedule A is a useful enforcement tool which conserves resources and which prevents lengthy judicial procedures because of its simple clarity.

There is no data on what the effect of eliminating Schedule A would be on health care costs or health outcomes. The World Health Organization supports the general concept of having a list of serious conditions for which drug advertising should not be allowed and which should only be treated by a qualified health practitioner

Options presented in this paper include: 1) to retain the prohibition but establish clear criteria for a disease to be listed; 2) same concept as that just described but in addition, to allow certain types of claims such as risk reduction claims; and 3) to eliminate the provisions related to Schedule A altogether.

1. ISSUE

The purpose of this Issue Paper is to determine whether the provisions relating to Section 3 and Schedule A should be kept in the proposed health protection legislation and if so, whether and how they should be amended.

2. BACKGROUND AND ISSUE ANALYSIS

Schedule A of the *Food and Drugs Act* lists a number of diseases, disorders or abnormal physical states for which treatments, preventatives, or cures cannot be advertised or sold to the general public. The provisions of the Act (Revised Statutes of Canada (R.S.C.), Chapter F-27, 1985) that refer to Schedule A are:

> 3. (1) No person shall advertise any food, drug, cosmetic or device to the general public as a treatment, preventative or cure for any of the diseases, disorders or abnormal physical states referred to in Schedule A.
>
> (2) No person shall sell any food, drug, cosmetic or device
> (a) that is represented by label, or
> (b) that the person advertises to the general public
>
> as a treatment, preventative or cure for any of the diseases, disorders or

abnormal physical states referred to in Schedule A.

Schedule A lists the 40 following conditions:

Alcoholism
Alopecia (except hereditary androgenetic alopecia)
Anxiety state
Appendicitis
Arteriosclerosis
Arthritis
Asthma
Bladder disease
Cancer
Convulsions
Depression
Diabetes
Disease of the prostate
Disorder of the menstrual flow
Dysentery
Edematous state
Epilepsy
Gall bladder disease
Gangrene
Glaucoma
Gout
Heart disease
Hernia
Hypertension
Hypotension
Impetigo
Kidney disease
Leukemia
Liver disease (except hepatitis)
Nausea and vomiting of pregnancy
Obesity
Pleurisy
Rheumatic fever
Septicemia
Sexual Impotence
Thrombotic and Embolic disorders
Thyroid disease
Tumor
Ulcer of the gastro-intestinal tract
Venereal disease

Section 30.(1)(j) of the Act grants the Governor in Council the authority to exempt any food, drug, cosmetic or device from all or any of the provisions of the Act.

Section 30.(1)(m) of the Act grants the authority to add anything to, or delete anything from Schedule A to the Act by way of regulations.

The *Food and Drugs Act* defines “advertisement” and “sell” as:

> ***Advertisement*** *includes any representation by any means whatever for the purpose of promoting directly or indirectly the sale or disposal of any food, drug, cosmetic or device;*
>
> ***Sell*** *includes offer for sale, expose for sale, have in possession for sale and distribute, whether or not the distribution is made for consideration;*

While allowing the dissemination of information about products for the treatment, prevention or cure for Schedule A conditions to health professionals, sections 3(1), 3(2) and Schedule A of the Act prevent the transmission of such information to the general public in the advertising and labelling of products.

It should be noted that since Section 3 does not mention “diagnosis”, advertising a product as a diagnostic for a Schedule A disease would technically be permitted.

2.1 Changes to Schedule A Throughout the Years

Schedule A is by no means static. Several conditions have been removed from it in recent years, under section 30.(1) (m), including: Scabies in 1988 (P.C. 1988-770); Influenza in 1990 (P.C. 1990-2003); Pneumonia, Poliomyelitis, Tetanus, and

Tuberculosis in 1992 (P.C. 1992-642); and vaginitis in 1994 (P.C. 1994-545). In addition, in 1999, "hereditary androgenetic alopecia" was exempted from "alopecia" and "hepatitis" was removed from "liver diseases". It is useful to consider why these conditions were removed from Schedule A.

The removal of vaginitis from Schedule A appears to have been prompted by the move of two antifungals, clotrimazole and miconazole, from prescription to non-prescription status (P.C. 1994-944). The reasons given for removing vaginitis from Schedule A were (P.C. 1994-545):

> *This amendment removes vaginitis from the disease conditions listed in Schedule A to the Food and Drugs Act. This permits clotrimazole and miconazole, preparations for the treatment of vaginal infection, to be promoted to the general public.*
>
> *The listing of vaginitis in Schedule A unduly restricts health promotional advertisement which is beneficial to women, and prevents self medication for topical antifungal preparations for the treatment of vaginal infections. Under the current regulatory requirements advertisements and labelling claims referencing vaginitis are in violation of subsection 3(1) of the Act.....*[1]

Prior to the removal of vaginitis from Schedule A, the two antifungals were both prescription drugs and as such they could not have been advertised to the general public as a treatment for vaginitis even if vaginitis had not been listed in Schedule A. Section C.01.044 of the Food and Drug Regulations restricts the advertising of prescription drugs to the general public:

> *C.01.044 (1) 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.*

It seems that sections 3(1), 3(2) and Schedule A of the Act are not necessary to prevent the advertising to the general public of prescription drugs, C.01.044 is sufficient. For products other than prescription drugs, however (food, over-the-counter drugs, natural health products, medical devices), there is no such provision. Advertising of nonprescription drugs is allowed to the general public as long as the section 9 prohibition against deception, false and misleading advertising, is respected.

Scabies was removed from Schedule A to permit the proper consumer labelling and advertising of nonprescription drugs available to treat the disease[2]. Although nonprescription drugs were available to treat scabies, so long as the disease was listed on Schedule A these drugs could not carry indications or directions for use relating to the treatment of this disease.

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[1] Canada Gazette Part II, Vol. 128, No 9. P.C.1994-545, p1754

[2] Canada Gazette Part II, Vol. 122, No. 10. P.C. 1988-770. p2427

Influenza, pneumonia, poliomyelitis, tetanus, tuberculosis, and hepatitis were all removed from Schedule A to allow for the promotion of vaccine prophylaxis and/or treatment to the general public in the interest of public health.[3] [4]

Asthma was added to Schedule A in 1989: This is the only condition that has been added in recent years[5]. According to the Regulatory Impact Analysis Statement (RIAS), asthma (a serious disease which can rapidly worsen and become life-threatening) was added because there had been reports of increased mortality from asthma and health professionals had recommended that the asthmatic patient be under the care of a physician. The Regulatory Impact Analysis Statement goes on to say:

> *This amendment adds asthma to the disease conditions listed in Schedule A to the Food and Drugs Act and, will ensure that products used for its prevention or treatment will not be advertised or offered for sale to the general public.*[6]

As for "hereditary androgenetic alopecia", its exemption was made at the same time as solutions of 2% or less of minoxidil for topical use were removed from Schedule F.

2.2 Rationale Behind Section 3 and Schedule A

The history of Schedule A since its inception is detailed in Appendix I. Throughout the years, four main reasons have been given to support and justify section 3 and Schedule A of the Act. They are described below:

2.2.1 To Prevent Fraud [7]

A benefit of Section 3 and Schedule A is that it makes it unnecessary to prove a drug is unsafe or valueless for one of the listed conditions, that it is harmful, or that the advertising is false or misleading. The section is an outright prohibition on representations for treatments of the conditions listed. Field inspectors consider Schedule A as a useful enforcement tool as it saves a lot of resources and prevents lengthy judicial procedures. Without this prohibition, more resources would be needed to deal with questionable claims related to Schedule A conditions.

On the other hand, we have been told during the consultations that fraud is adequately

---

[3] Canada Gazette Part II, Vol. 124, No. 21, P.C. 1990-2003, p.4204.

[4] Canada Gazette Part II, Vol. 126, No. 9, P.C. 1992-641, p1442.

[5] In fact, at the same time asthma was added to Schedule A, aminophylline and other methylxanthines were added to Schedule F so that these drugs (which are used in the treatment of asthma and have a low therapeutic margin) would only be available following the prescription of a practitioner.

[6] Canada Gazette Part II, Vol. 123, No. 23, P.C. 1989-2100, p4516-4518.

[7] R.E. Curran, Canada's Food and Drug Laws, Commerce Clearing House Inc., 1953, p. 188.

addressed in other provisions of the *Food and Drugs Act,* such as sections 5, 9, and 20, and that it is not necessary for a condition to be listed on Schedule A to prevent fraudulent sale of treatments, preventatives or cures for the condition. In that respect, Section 9, for example, reads:

> *9.(1) 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 character, value, quantity, composition, merit or safety.*

In other words, the outright prohibition on promotional material, as provided by Schedule A, may not be necessary. This argument has been used to support the removal of several diseases from Schedule A.

2.2.2 To Prohibit the Advertisement and Sale of Treatments for Conditions Where No Treatment Is Known to Medical Science [8]

Back in 1934, when Schedule A was introduced, there were no known effective treatments for most diseases. This is no longer the case given the progress of medical science. Schedule A lists diseases for which treatments, preventatives or cures now do exist. Given the potential of frontier products such as gene therapy, treatments may soon exist for diseases that are currently not treatable. It appears that the lack of known treatment for a disease is no longer a good criteria for Schedule A listing.

2.2.3 To Prohibit the Advertisement and Sale of Treatments Where Self Treatment Is Not Considered Safe [9]

When considering the relevance of Section 3 and Schedule A, it is important to consider the legislative and regulatory environment which existed in 1934 when these provisions came into being. Prior to a 1939 amendment to the *Food and Drugs Act*, there were very few restrictions on the public's access to drugs. It was not until 1941 that a prescription was required for the purchase of barbiturates, amphetamine, sulphonamides and various other drugs. Antibiotics such as penicillin were not regulated until 1946, when the *Food and Drugs Act* was further amended allowing for their control. Therefore, back in 1934, in the absence of a prescription regime, Schedule A was the only way to restrict access to drugs that were not safe for self-treatment because of their toxicity, low therapeutic margin, potential for abuse, etc..

> *"The main reasons for requiring additional control of prescription drugs are the need for professional direction and supervision in their use and, in some cases, the need to minimize the potential for misuse or abuse."*[10]

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[8] R.E. Curran, Canada's Food and Drug Laws, Commerce Clearing House Inc., 1953, p. 188.

[9] Ibid.

[10] Health and Welfare Canada, Health Protection and Drug Laws - 1991 Edition, Ottawa 1991. p19

The fact that professional direction and supervision is now required for the purchase of prescription drugs helps ensure the drugs are used in a safe manner. Advertising of prescription drugs is also restricted, as was discussed above. Prescription status for a drug accomplishes the aim of preventing self-diagnosis and treatment without actually having to list the disease condition on Schedule A. In the United States, prescription status for drugs came into being because "the FDA determined that consumers were unable to choose some drugs for safe self medication".[11] According to the United States definition, a prescription drug is one which "because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner....".[12] In the United States, requiring a prescription for a drug is considered to accomplish the same goals as Schedule A.

We heard from an interested party that in the current legislative and regulatory framework, it is difficult to conceive of a situation where the restrictions imposed by Section 3 of the Act would be key in controlling a risk to public health.

2.2.4 To Encourage People to Seek Medical Attention for Serious Conditions [13]

Also relevant to the consideration of Schedule A is the health care system of the era. At the time Schedule A was added to the *Food and Drugs Act*, Canada did not have universal medicare. This is significant in that an individual wishing to see a physician would have to pay for the services provided. During the depression of the 1930's “Medical care, except in the direst emergency conditions, was a luxury that only few individuals or municipalities could afford”.[14] A 1933 survey by the Canadian Medical Association revealed that only a few municipalities could meet the medical costs they were faced with. Most provinces were in a similar position.[15] A logical consequence of this situation was a greater tendency to self-diagnose and self-medicate among those who were unable or disinclined to pay for a physician's services. This in turn made people more susceptible to charlatans claiming to have cures for various ailments.

While there is merit in encouraging people to seek prompt medical attention for serious conditions, some view it as paternalistic to try to coerce people to seek that attention. It

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[11] Charles J. Walsh, The Learned Intermediary Doctrine: The Correct Prescription for Drug Labelling, Rutgers Law Review, Vol.48, No.3, 1996.

[12] 21 U.S.C. 353(b)(1)(B) (1994)

[13] A. Linton Davidson, The Genesis and Growth of Food and Drug Administration in Canada, 1950, p. 75.

[14] Malcolm G. Taylor, Health Insurance and Canadian Public Policy. The Seven Decisions That Created the Canadian Health Insurance System and Their Outcomes. McGill-Queen’s University Press, 1978. p.4

[15] Ibid.

has been argued that given the increasing popularity and acceptance of self-medication, alternative health care and the desire of Canadians to take charge of their own health, people should be able to choose the type of treatment they want. However, many people believe that for serious diseases, patients need the intervention of a health professional to diagnose, treat and monitor the progression of the disease.

As mentioned, there are conditions listed in Schedule A for which non-prescription drugs are available, for example, diabetes and heart disease. Diabetes is treated with insulin which is a non-prescription drug. Angina, which can be included under the broad category of heart disease, is treated with nitroglycerin which is also a non-prescription drug. Insulin and nitroglycerin both fall into the group of non-prescription drugs that should only be used in consultation with a physician and are stored behind the counter in a pharmacy.[16]

2.2.5 Summary

To summarize, according to the sources cited, Section 3 and Schedule A were added to the Act:

- to prevent fraud, for those conditions that had caused previous advertising and labelling problems;
- to prohibit advertisements to the public respecting treatment for conditions where no treatment existed;
- to prohibit the advertisements and sale of treatments where self-treatment was not considered proper or safe; and
- to encourage people to seek medical attention for serious conditions.

Of these four reasons given to justify Schedule A over the years, it appears that only the last one might still retain some validity today. Some people question whether it is still desirable to prevent the self diagnoses and the self treatment and self monitoring of diseases such as cancer and diabetes. They also debate whether it is appropriate to prohibit claims on products for serious diseases because these conditions should be treated by a health professional. Others are asking whether it is appropriate to implicitly suggest the intervention of a health professional for a serious disease. On the other hand, most agree that serious diseases that are not properly diagnosed, treated and monitored can have disastrous effects on the health of individuals.

2.3 Issues to Consider

2.3.1 Restriction on the Dissemination of Information

[16] The explanation for this is that insulin and nitroglycerin are exceptions: both drugs meet the criteria for listing drugs in Schedule F, but they are exempted because they are rarely used without the supervision of a practitioner, and the need for their free availability outweighs the need for protection under Schedule F. Appendix III, "Factors for Listing Drugs in Schedule F", "Schedule F: The Listing and Delisting of Prescription Drugs", Draft Policy, Bureau of Policy and Coordination, Therapeutic Products Programme.

Although Section 3 and Schedule A do not apply to general information about diseases, they limit the claims that can be made for a product on its labelling material, which is considered by many people to be a source of information.

Some interested parties suggest that the wealth of information available to the public on the Internet, through books, literature, etc. has rendered Schedule A outdated to some extent. They advocate the removal of Schedule A from the *Food and Drugs Act* because of the quantity of information available, the right of consumers to full information, and the high level of awareness of the general public.

2.3.2 Criteria for Listing Diseases

Some interested parties are of the view that Schedule A should be eliminated because no satisfactory criteria exists to determine what should be in it and that it is therefore arbitrary. Currently, Schedule A contains an inconsistent list of conditions: some are not serious (e.g. alopecia), while serious diseases like Parkinson's and Multiple Sclerosis are not listed.

It has been suggested that an advisory committee composed of experts could use criteria such as the following to determine which conditions should be included on the list:

- the condition could cause important bodily harm or death particularly if not adequately diagnosed, treated or monitored in due time by a qualified health practitioner.

2.3.3 Pre-Clearance of Products

Some interested parties have presented the view that under the provisions of *the Food and Drugs Act*, as soon as a medical claim is made for a substance or mixture of substances, it becomes a drug and must be "approved", i.e., go through some kind of pre-market review during which unacceptable/unsupported claims are removed. There is a belief among some that this pre-market process makes Schedule A unnecessary. In fact, this is not the case for all commodities covered by the Act. Most foods, low risk medical devices (Class I and II), and cosmetics do not have to go through pre-market review. In addition, the fact that products are subject to pre-market review does not prevent their marketing with promotional material differing from the material that was originally approved.

2.3.4 General Public

Section 3 prohibits the advertising of a product to the general public as a treatment, preventative, or cure for any of the listed conditions. What if the promotional material is not directed to the general public, but to a sub-group of individuals, e.g., the distributors of a product? Because "general public" is not defined in the Act or the regulations, its usual meaning has to be used in the interpretation of section 3. Sub-groups of the general public are not considered to be the "general public". Consequently, when

promotional material with Schedule A claims is distributed to sub-groups of the general public, e.g. association of patients, wholesalers, distributors, etc., section 3 does not apply.

This limits the applicability of section 3 and Schedule A, and some suppliers have exploited this nuance.

2.3.5 Lack of Data on the Effects of Eliminating Schedule A

It is not known what the effects (e.g. benefits, risks, costs to individuals and to the health care system) of eliminating Schedule A would be. For those who view Schedule A as limiting unnecessary or high cost treatments and medical visits, and also as limiting the demand for drugs, the elimination of the schedule might increase health care costs. Others argue that the important factor is whether the change would result in improved health outcomes for Canadians.

2.3.6 Impact on Department/ Resources

The elimination of Schedule A would be likely to increase the workload of inspectors and make their work more difficult as they would have only the deception provisions to rely on in order to obtain compliance. The deception provisions would also have to be significantly reinforced. Even in the case where the deception prohibition was reinforced to include a requirement for data to support any health claim, there would still be debate as to what constitutes acceptable data.

2.3.7 Enforcement

The enforcement of Schedule A poses a challenge as it does not allow inspectors to deal with indirect claims. In addition, Schedule A claims reach Canadians through the direct to consumer advertising for prescription drugs in the United States via print and television. Further, Internet advertising is essentially un-vetted. Although the Therapeutic Products Programme has jurisdiction over advertising originating in any country if it is distributed within the boundaries of Canada, it has no jurisdiction on advertising originating outside Canada where all sales and representations are made from a location or agent outside of Canada.

2.4 Consultations

The following is a summary of the comments we have received on Schedule A during the national and internal consultations. The consultations indicated support for both maintaining and eliminating the Schedule.

- *"Schedule A should be retained but updated and revised to include new categories of products (including natural health products) and to eliminate inconsistencies. This should be done with the help of medical experts."*

- *"Schedule A has outlived its usefulness. Information concerning drugs is readily available from references such as the CPS (Compendium of Pharmaceutical Specialties) and the Internet."*

- *"Schedule A should be eliminated because given the pace of change, it quickly becomes obsolete. As well, there are better ways to prevent false claims."*

- *"Schedule A should be moved from the Food and Drugs Act to the Regulations so that it can be applied with greater flexibility."*

- *"An option would be to use Schedule A to list all diseases, and whether or not there are treatments or not. This list could be amended as need be to be a current list of all diseases. That list could in turn be used to determine the "medically necessary" treatments for those diseases covered under the Canada Health Act. These diseases would also serve as the basis for restricting advertising of products to treat them, though objective information about products in general would be allowed."*

- *"The prohibition created by Section 3 and Schedule A of the current Food & Drugs Act is total and unqualified. Even in the case of a proven claim, linking the claim with a specific product results in a violation of the law. Without revocation or amendment through regulations, Section 3 (Schedule A) will continue to serve as a major constraint to the use of health messages."*

- *"Schedule A should be removed from the Food and Drugs Act. This schedule is obsolete, is unnecessary and does not adequately protect the public against drug misuse. In addition, Schedule A prevents the dissemination of information on products of benefit to the health of Canadians.*"

- *"Yes, there should continue to be restrictions based on Schedule A. Criteria should involve considerations of the need for patients to seek expert advice from their physician regarding the treatment of the disease. Expert medical opinion should be used during review of diseases for inclusion or exclusion from Schedule A."*

- *"Determine criteria (for inclusion in Schedule A) by expert and public input and multi stakeholder panel."*

- *Yes (there should continue to be restrictions) - for the protection of the health and safety of the members of our population and to encourage people to seek professional health advice rather than to "self-treat" and "self medicate" ... The list on Schedule A should be reviewed by competent people.*

- *Yes. Restrictions should continue. Schedule A should be revised with the assistance of perhaps the Canadian Medical Association or some other appropriate organization*

- *Continue restriction, but our borders are porous with American advertising.*

- *Why hasn't Schedule A been revised? By all means review it.*

- *Yes, promotion of therapeutic products to the general public should be restricted to those that have been proven to be effective.*

- *I think consumers rely on restrictions in advertising and it is necessary. Unnecessary advertising, false claims, or creating "trendy" drugs through advertising is very dangerous.*

2.5 International Comparison

2.5.1 United States

As noted by Curran[17], no provisions similar to Section 3 and Schedule A of *the Food and Drugs Act* appear in the *Food, Drug and Cosmetic Act* of the United States. In the United States the *Copeland Act* (S.2800) Section 9 c), as it was introduced, contained a proposal similar to Section 3 of the *Food and Drugs Act*. This section of the Act, which deemed an advertisement to be false if it represented a treatment for any of a number of diseases listed, was not included in the legislation as it was finally passed. Claims considered to be false or misleading would constitute a violation of Sec. 502 (Misbranded Drugs and Devices) of the US Federal *Food, Drug and Cosmetic Act*.

Although not a statutory requirement, the US FDA does provide guidance that is similar in effect to Section 3 of the Canadian *Food and Drugs Act*. In reference to Sec. 502 of the US Federal *Food, Drug, and Cosmetic Act*, mentioned above, the FDA has stated:

> A drug should be recommended for use only for those conditions which have been shown by scientific tests to be effectively treated by the drug. Serious conditions which cannot be diagnosed or successfully treated by consumers should not be referred to in labelling of over-the-counter drugs.[18]

2.5.2 European Union

Several members of the European Union including Belgium, Ireland, the UK, Spain and Portugal all place restrictions on the advertising of products for treating particular illnesses[19]. As an example, the relevant section of the UK *Medicines Act* 1968 provides:

> *(95) Powers to regulate advertisements and representations*
>
> *(1) The appropriate Ministers may by regulations prohibit any one or more of the following, that is to say-*
>
> *a) the issue of advertisements relating to medicinal products of a particular description or falling within a class specified in the regulations;*

---

[17] Robert E. Curran was the Legal Adviser to Canada's Department of National Health and Welfare from 1945 on, and the author of the book:"Canada's Food and Drug Laws".

[18] Requirements of laws and regulations enforced by the U.S. Food and Drug Administration. Available from http://www.fda.gov/opacom/morechoices/smallbusiness/bluebook.html

[19] PLR pharma law reports, Advertising and Promotion for Pharmaceuticals, EPLC Pharma Law Report No 2. Summary available from: http://www.pjbpubs.co.uk/epic/advert.html

> *b) the issue of advertisements likely to lead to the use of any medicinal product, or any other substance or article, for the purpose of treating or preventing a disease specified in the regulations or for the purpose of diagnosis of a disease so specified or of ascertaining the existence, degree or extent of a physiological condition so specified or of permanently or temporarily preventing or otherwise interfering with the normal operation of a physiological function so specified, or for the purpose of artificially inducing a condition of body or mind so specified;*
>
> *c) the issue of advertisements likely to lead to the use of medicinal products of a particular description or falling within a particular class specified in the regulations, or the use of any other substance or article of a description or class so specified, for any such purpose as is mentioned in paragraph (b) of this subsection;*
>
> *d) the issue of advertisements relating to medicinal products and containing a word or phrase specified in the regulations, as being a word or phrase which, in the opinion of the appropriate Ministers, is likely to mislead the public as to the nature or effects of the products or as to any condition of body or mind in connection with which the products might be used.*[20]

This is similar in scope and effect to section 3 of the Canadian *Food and Drugs Act*.

2.5.3 Australia

Only those products which are available without prescription may be advertised to the general public. Advertisements in radio, television, cinema, newspapers, magazines, etc. require formal approval before they can be broadcasted, exhibited, published or displayed. Advertisements in newspapers and magazines are given an approval number which must be displayed. [21]

There are two types of limitations: the Prohibited Representations, and the Restricted Representations.

Prohibited representations: A prohibited representation is defined as:

- any representation regarding abortifacient action;
- any representation regarding the treatment, cure or prevention of the

[20] *Medicines Act* 1968 (1968 c67)

[21] Therapeutic Goods Advertising Code Council, http://www.tgac.com.au/index.cfm

following diseases: Neoplastic, Sexually Transmitted Diseases (STD), HIV AIDS and/or HCV, and Mental Illness,

Except for the following representations which are to become Restricted Representations:

- prevention of skin cancer through the use of sun screens; and
- devices used in contraception or in the prevention of transmission of disease between persons.

Restricted Representations: An advertisement for therapeutic goods may refer, expressly or by implication, to a disease, condition, ailment or defect specified in Table 1, provided that prior approval is obtained for such a reference. Approval may be obtained from the TGA, upon recommendation from the TGACC and appropriate expert committee or committees.

Table 1 lists the following diseases, conditions, ailments and defects for which the advertising of serious forms is restricted:

- Cardiovascular diseases
- Dental and periodontal diseases
- Diseases of joint, bone, collagen, and rheumatic disease
- Diseases of the eye or ear likely to lead to blindness or deafness
- Diseases of the liver, biliary system or pancreas
- Endocrine diseases and conditions including diabetes and prostatic disease
- Gastrointestinal diseases or disorders
- Haematological diseases
- Infectious diseases
- Immunological diseases
- Mental disturbances
- Metabolic disorders
- Musculo-skeletal diseases
- Nervous system diseases
- Poisoning, venomous bites and stings
- Renal diseases
- Respiratory diseases
- Skin diseases
- Substance dependence
- Urogenital diseases and conditions

2.6 World Health Organization

The World Health Organization's Ethical Criteria for Medicinal Drug Promotion, Resolution WHA41.17 adopted by the Forty-first World Health Assembly, 13 May 1988, states:

> (14). Advertisements to the general public should help people to make rational decisions on the use of drugs determined to be legally available without a prescription..... They (i.e. advertisements) should not generally be permitted for prescription drugs or to

> promote drugs for certain serious conditions that can be treated only by qualified health practitioners, for which certain countries have established lists.[22]

The WHO document also describes its intended scope of applicability:

> (4). These criteria constitute general principles for ethical standards which could be adopted by governments to national circumstances as appropriate to their political, economic, cultural, social, educational, scientific and technical situation, laws and regulations, disease profile, therapeutic traditions and the level of development of their health system. **They apply to prescription and non-prescription medicinal drugs (over-the-counter drugs). They also apply generally to traditional medicines as appropriate, and to any other product promoted as a medicine.**[23](emphasis added)

2.7 Report of the Standing Committee on Health

The House of Commons Standing Committee presented its report on natural health products in November 1998.[24] In chapter 7, which discusses Section 3 and Schedule A of the *Food and Drugs Act*, the Committee felt that current provisions may unduly restrict health promotional advertisement that may be beneficial to consumers and may prevent self-medication in cases where it is warranted. The committee made the following recommendations:

> *Health Canada immediately initiate a review of the diseases listed in Schedule A to ensure that only appropriate diseases are included and, where relevant, specific diseases be exempted by regulations from the broad terms found in Schedule A;*
>
> *Health Canada, subsequently, 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.*

2.8 Final Report of the Advisory Panel on Natural Health Products

In its report, the Panel felt that the provisions of Schedule A are outdated and recommends that it be rescinded immediately: "... at a time when consumers are demanding greater choice in health care, Schedule A poses a needless and onerous

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[22] WHO Ethical Criteria for Medicinal Drug Promotion, World Health Organization, Geneva 1988. Full text available in EDM-17 Drug Promotion, from http://www.who.int/medicines/library/monitor/edm17a.html

[23] Ibid

[24] "Natural Health Products: A new Vision", Report of the Standing Committee on Health, available at: http://www.parl.gc.ca/InfoComDoc/HEAL/Studies/Reports/healrp02-e.htm

restriction." [25]

3. OPTION ANALYSIS

3.1 Option 1

The proposed Act could:

- prohibit the promotion to any member of the general public of any product as a means to diagnose, prevent, treat or cure a condition listed in a schedule established by the Governor in Council (Cabinet) in Regulations; and

- establish that in order to be listed in the so-called "Schedule A", a condition must be one that could cause important bodily harm or death, particularly if not diagnosed, treated or monitored in due time by a qualified health practitioner.

Pros:

- Encourages people to seek medical attention.
- The criteria will make the process of listing a condition less arbitrary and more transparent.
- For those conditions remaining on Schedule A, enforcement is simple, fast, and does not require interpretation, discussion, data evaluation, court cases, significant delays, etc.
- Helps protect consumer from fraud when efficiently enforced.

Cons:

- The violations involving conditions removed from the list will take more effort to resolve.
- Raises the issue of standard of evidence for those conditions not found on the list: what evidence would be required to support a claim?

3.2 Option 2

The proposed Act could:

Contain the main provisions of Option 1 above, but instead of containing an outright prohibition, have some flexibility with respect to the type of claim which may or may not be allowed (e.g. allow for certain risk reduction claims).

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[25] Regulatory Framework for Natural Health Products, Final Report of the Advisory Panel on Natural Health Products, May 13, 1998.

The regulations could specify what representations are allowed or the Minister could be granted the power to authorize certain claims on a case-by-case basis.

Pros:

- Encourages people to seek medical attention.
- The criteria will make the process of listing a condition less arbitrary and more transparent.
- For those conditions remaining on Schedule A, enforcement is simple, fast, and does not require interpretation, discussion, data evaluation, court cases, significant delays, etc.
- Helps protect consumer from fraud when efficiently enforced.
- Allows for health claims which are beneficial to public health to be made.

Cons:

- The violations involving conditions removed from the list will take more effort to resolve.
- Raises the issue of standard of evidence for those conditions not found on the list: what evidence would be required to support a claim? Would the amount of evidence vary depending on whether the claim is risk-reduction or therapeutic (prevent, treat, etc.)?

3.3 Option 3

The existing provisions relating to “Schedule A” could be eliminated altogether.

Pros:

- Helps ensure that the consumer is educated, has a right to information and is capable of evaluating the information provided on drugs, even for conditions which cannot be self-diagnosed, self-treated, and self-monitored.
- The Schedule A criteria could be built into the criteria for direct to consumer advertising. In other words, when claims would be made for serious conditions, the consumer would be encouraged to consult a health professional.

Cons:

- Makes enforcement more difficult as the data supporting the unfounded/violative claims need to be evaluated. In the absence of Schedule A, the deception prohibition would have to be significantly strengthened to avoid spending resources reviewing equivocal data. Without a strong deception prohibition, the advertising that

will result with the elimination of Schedule A may increase the cases of fraud.

- In the absence of Schedule A, disputes as to the validity of a claim may end up in court more often.
- Makes it possible for an over the counter product or a natural health product to make a claim for a serious disease which is not in line with the Criteria for Nonprescription Status of the Therapeutic Products Programme which stipulates that for a drug to have nonprescription status it must, amongst other things be indicated for conditions which can be self-diagnosed, self-treated, and self-monitored.
- Raises the issue of standard of evidence: what evidence would be required to support a claim? Would the amount of evidence vary depending on whether the claim is risk-reduction or therapeutic (prevent, treat, etc...)?

APPENDIX I - Origin of Schedule A

It is useful to review the history of Schedule A in order to understand the reasons that were given to justify its addition to the Act and to maintain it in the Act throughout the years.

The section of the Act referring to Schedule A was introduced as Section 6A in 1934 C-54). It was renumbered as Section 7 in the revised statutes of 1952 C-123), and was renumbered again as Section 3 when the legislation was extensively revised in 1953 C-38). In the current legislation the wording of sub-sections 3(1) and 3(2) is identical to the wording from 1953. The only change to Section 3 since 1953 is the addition of sub-section 3(3) restricting the advertisement of contraceptives. To avoid confusion, the sections of the Act prohibiting the advertising and sale of treatments for Schedule A conditions will be referred to as Section 3 of the Act throughout this document, except where the history of these provisions is considered.

According to A. Linton Davidson, section 6A, which refers to Schedule A was added to the *Food and Drugs Act* in 1934[26] to address weaknesses in the Act pertaining to the misbranding[27] of drugs.[28] At that time, false or misleading claims were regulated under section 7:

> *7. Food or drug shall be deemed to be misbranded within the meaning of this Act*
>
> *(e) if false or exaggerated claims are made for it upon the label or otherwise;*[29]

Whether a claim was false or exaggerated was ultimately for the courts to decide, not the Department. The court's decision could be complicated by the presentation of "expert" evidence on behalf of the defense claiming that the drug in question was prescribed by physicians everywhere for the condition(s) indicated, i.e. how could the claim be exaggerated if physicians everywhere prescribed it for that condition? To avoid arguments about whether a claim was false or exaggerated, section 6A was added to the Act:

> *6A. No person shall import, offer for sale, or sell any remedy represented by label or by advertisement to the general public as a treatment for any of the diseases,*

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[26] R.E. Curran, Canada's Food and Drug Laws, Commerce Clearing House Inc., 1953, p288

[27] Early Canadian Food and Drug legislation was concerned primarily with adulteration. A statutory definition of misbranding was introduced to the *Food and Drugs Act* in 1920 but applied only to food. Misbranding was extended to drugs in 1927. Most of offenses that were deemed to constitute misbranding were related to fraud (representing the product as something it was not).

[28] A . Linton Davidson, The Genesis and Growth of Food and Drug Administration in Canada. 1950. p75

[29] Revised Statutes of Canada (R.S.C.), C-76, 1927

disorders or abnormal physical states named or included in Schedule A to this Act or in any amendment to such Schedule. [30]

In reference to Schedule A conditions Davidson states:

...the fundamental consideration is that such conditions should be under medical supervision as soon as known, so that valuable time may not be wasted by lay-people experimenting with this remedy or that.[31]

The origin of Schedule A is also considered by Robert E. Curran.[32] In the revised statutes of 1952 (Chapter 123), section 6A was renumbered as section 7. In discussing this section Curran notes:

The purpose of the section is to prevent advertisements to the public respecting treatment for conditions where either no treatment is known to medical science or where self-treatment is not considered proper or safe.[33]

It should be noted that there is also a strong anti-fraud element in Section 3 of the Act. Curran states that in addition to "conditions where either no treatment is known to medical science or where self-treatment is not considered proper or safe"[34], Schedule A lists conditions which "have been found fruitful sources of revenue for the quack and the charlatan."[35] The prevention of fraud by this section of the Act was mentioned in the House of Commons by Paul Martin, the then Minister of Health and Welfare when the Act (of 1953) was being debated. In reference to the advertisement of treatments and cures for cancer the minister stated; "That is a fraud on the public, and this measure seeks to prevent that."[36]

L.I. Pugsley also comments on Schedule A:

This provision proved to be a most effective method of controlling the advertising of drugs for a group of diseases which require medical diagnosis and treatment. These are

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[30] C-54, 1934.

[31] A. Linton Davidson, The Genesis and Growth of Food and Drug Administration in Canada. 1950. p75

[32] Aside from writing a book entitled Canada's Food and Drug Laws on the history of the *Food and Drugs Act*, Curran was the Legal Adviser to Health Canada's Department of National Health and Welfare when the *Food and Drugs Act* was adopted in 1953.

[33] R.E. Curran, Canada's Food and Drug Laws, Commerce Clearing House Inc., 1953, p.188

[34] Ibid.

[35] Ibid.

[36] Hon. Paul Martin (Minister of National Health and Welfare), Hansard April 21st 1953.

> *diseases for which self-diagnosis and self-treatment are considered not to be in the best interests of the general public.*[37]

According to Regulatory Impact Analysis Statements (RIAS) accompanying proposed changes to Schedule A, "Schedule A to the *Food and Drugs Act* lists diseases which can only be properly diagnosed and treated by a physician, or for which there is no known treatment".[38]

[37] L.I. Pugsley, Medical Services Journal, Canada, Vol. XXIII, NO. 3, pages 387-449, March 1967.

[38] Canada Gazette Part II, Vol. 122. No. 10, P.C. 1988-770, p2427.