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# Section 3 & Schedule A of the Food and Drugs Act

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## EXECUTIVE SUMMARY

Section 3 of the *Food and Drugs Act* prohibits the advertising to the general public of any food, drug, cosmetic or device for the treatment, prevention or cure of any of the diseases listed on Schedule A of the *Food and Drugs Act*. This section of the Act also prohibits the sale of a food, drug, cosmetic or device that is labeled in this manner.

In its 1998 report on the legislative and regulatory regime governing natural health products, the House of Commons Standing Committee on Health found that the current provisions under Section 3 and Schedule A of the Act may unduly restrict health promotional advertisement that may be beneficial to consumers and may prevent self-medication in cases where it is warranted. In response to the Committee’s recommendations, this External Working Group was established in February 2003 to provide recommendations on modifications and amendments to, or elimination of, Schedule A and Section 3 of the *Food and Drugs Act*. The Working Group was specifically mandated to:

- 1) Review Schedule A list of diseases;
- 2) Provide recommendations for both short-and long-term processes; and,
- 3) Prepare a report as the basis for broader public consultation by Health Canada. The proposal by the WG may include, but not be limited to:
  - Criteria that can be used for determining which diseases ought to be included in Schedule A;
  - Modifications (including addition, removal, renaming, or further clarification of Schedule A diseases) or elimination of Schedule A; and,
  - Proposals for certain products or classes of products to be exempted from the application of Section 3 of the *Food and Drugs Act*.

The External Working Group consisted of representatives from government and regulatory groups, professional associations, consumer/advocacy group, advertising, media, foods, health products and medical devices. Representatives were nominated by their respective organizations due to their expertise in various areas related to Schedule A. As such, the views expressed in the report are expert opinions of the individual members and do not necessarily reflect the organizations which nominated them. Members brought diverse experiences, perspectives and values to table, and towards fulfilling their mandate. This diversity furthered the analysis and rendered the report more reflective of the various views in Canadian society. Although many members shared similar views with respect to changes to Section 3 and Schedule A, others expressed differing opinions. It became clear that some of the differences amongst the members were of a fundamental nature. For example, while most of the members agreed that provisions in Section 3 and Schedule A unduly restrict some health promotional advertisement and may prevent self-medication where warranted, others were against any advertising on products making health claims. This report reflects the thinking of the Working Group as a whole and identifies where we reached consensus and where our opinions differed.

At the outset, the Working Group recognized that the issues before it were complex and would encourage much debate. For this reason and to ensure consistency in decisions, the group adopted the following set of guiding principles:

1. 1. Protect the safety of consumers
2. 2. Optimize health outcomes
3. 3. Improve access to complete, relevant truthful and validated health information
4. 4. Use evidence-based decision making, which incorporates dynamic and flexible solutions
5. 5. Facilitate responsible self-care and assisted-care decisions, and patient-practitioner discussions

Over the months, the Working Group met 6 times, engaged in a number of teleconferences as subgroups, and reviewed various analytical research pieces as well as international approaches to the regulation of products making health claims.

In assessing Section 3 and Schedule A, the Working Group also

considered the historical context in which these provisions were introduced in 1934, and retained in the *Food and Drugs Act* in 1952 and again in 1953. Social conditions, absence of regulatory and legislative controls against fraud, and the absence of a universal health-care system at the time, were assessed against the current regulatory environment, the current health-care system, public access to information, mass media, the role of health-care charities and advocacy groups, and societal attitudes towards and expectations from the health-care system. Although direct to consumer advertising of prescription drugs was not within the mandate of the Working Group, members felt that because Canadians are already exposed to internet and cross border media advertising for Schedule A diseases, the issue had some bearing on the discussions.

Discussions around advertising often highlighted the value of consumer education as a basis for informed decision-making. Many members viewed education as an important compliment to advertising of health products. They emphasized the need for effective funding mechanisms to support educational programs. A strong post-market surveillance program is a critical element for assessing the impact on patients of health products for ensuring safety and effectiveness.

In developing its recommendations, the Working Group found the following issues to be relevant to its mandate:

- With advances in health care, treatment for many of the diseases listed in Schedule A is now available. Though there is still no known cure for many of the diseases listed in Schedule A, such as arthritis and diabetes, modern therapies allow these chronic conditions to be successfully managed. For example, a product could lessen discomfort caused by a condition or slow the progression of a disease. In addition, with the potential of new groups of products such as those stemming from gene therapy, treatments may soon be available for diseases that are not currently treatable.
- Despite the paradigm shift towards self-care, holism and patients' increasing involvement in choice of treatment, there is still an important role for the medical diagnosis, treatment and monitoring of serious diseases.
- Over the years, co-existing regulations, both in law (Schedule F; Sections 5, 9 and 20) and through voluntary industry codes (Advertising Standards Canada etc.) have been developed against fraud

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in labeling, advertising and sale of treatments. In addition, the current pre-market regulatory system only allows evidence-based health claims on foods, and medical devices. Health products such as pharmaceuticals and natural health products must undergo a pre-market evaluation to obtain a license to sell.

- The enforcement of existing or amended regulations would require a

significant and ongoing investment of resources.

Consistent with the Standing Committee on Health recommendations, the Working Group unanimously agreed that Section 3 and Schedule A needed to be amended to meet the needs of the current Canadian society. However, there were differences in opinion as what is the best approach to make such changes.

The Working Group recommends phased-in modifications to Schedule A and Section 3 through administrative amendments in the short-term, regulatory amendments in the medium-term, and long-term options related to legislative amendments. The long-term options are proposed to be taken into consideration in the development of Health Canada's proposed new Canada Health Protection Act. Most Working Group members support these recommendations. The views of those members who have expressed diverse opinions are also reflected. There was strong consensus among the members that with any legislative and regulatory regime in place, there must be adequate resources for enforcement.

### **Recommendation 1 – Short-term Administrative Amendments: Revise Health Canada's Guidance Document on Section 3 and Schedule A**

The terms "Treatment", "Preventative" and "Cure" are not defined in the Act or the Regulations. The majority of the External Working Group members recommend that, in the short term, Health Canada revise the guidance document to include:

- Definitions of "Treatment", "Preventative", "Cure", "Symptomatic Treatment" and "Risk Reduction", to clarify distinction between product claims that are prohibited and those that are allowed. Proposed definitions supported by the majority of the members would prohibit claims that would create the impression of absolute prevention of the disease. The majority supports the current interpretation that permits claims for the relief of symptoms associated with Schedule A diseases such as arthritic pain relief. Likewise, proposed definitions would separate risk reduction from prevention and allow for risk-reduction claims, provided there is evidence to support such claims.
- Clarifications of disease nomenclature to ensure proper interpretation for evaluation of claims. While there was consensus on this recommendation, the members felt that they did not have the appropriate expertise for this exercise.

All members of the group were of the opinion that revisions to Health Canada's guidance document should follow a public consultation process. Some felt that no advertising changes should be undertaken. They also opposed some of the current interpretations such as allowing 'symptomatic treatment' claims. The group held the view that proper control was necessary to ensure that risk reduction claims would not likely be interpreted as 'prevention' or 'treatment' claims by consumers.

## **Recommendation 2 – Medium-term Regulatory Amendments to Schedule A**

The Working Group recommends that, in the medium-term, Health Canada:

- Replace the current Schedule A with a shorter list of diseases; and,
- Establish a set of criteria for review of Schedule A diseases.

The Working Group examined a number of criteria for review of Schedule A. In the final analysis, most members agreed that the following set is comprehensive and provides a sound basis for future review:

1. The disease state results in a serious public health risk and is likely to lead to the spread of the disease without appropriate treatment.
2. The disease requires emergency care where self-care is inappropriate.
3. The severity of the disease limits the person's ability to make health decisions.
4. The disease state is new and still under investigation.

Accordingly, members of the Working Group engaged in an initial review of the current Schedule A list of diseases applying the above criteria and retained nine diseases out of forty in the list. It was recommended that a further review of the list of diseases should be undertaken by experts in the particular fields, Health Canada, and through public consultations.

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Others were of the view that adding the following criteria to the above would improve the government's ability to prohibit product-specific advertising on public health grounds.

- The disease or condition is one which renders individuals especially vulnerable to harm from unnecessary exposure to drugs and other health care products.

## **Recommendation 3 – Long-term Legislative Changes to Section 3 and Schedule A**

Most Working Group members were of the opinion that today's regulatory system adequately addresses product safety, quality and efficacy and has rendered Schedule A redundant and a limitation on consumer's access to truthful information. They felt that the real solution lies in a legislative change to correct the fundamental problem with the current law. A few oppose any changes to the current *Food and Drugs Act*.

Most Working Group members have agreed to propose the following two long-term legislative options to be considered as a part of legislative renewal. Option 1 proposes the complete elimination of Section 3 and Schedule A.

Option 2 proposes that Schedule A be removed and Section 3 of the Act be amended to establish controls on advertising to any member of the general public for products covered by the Act, to diagnose, prevent, treat or cure a disease or condition.

#### **Recommendation 4— Ensuring Adequate Resources for Enforcement**

The Working Group recognized that the recommendations in this report would relax current restrictions on advertising of health claims and could lead to a substantial increase in the overall advertising for health products. With this recognition, it was considered important to strengthen safeguards against a potential increase in fraudulent, deceptive or misleading health claims.

Members noted that enforcement must be targeted at this overarching advertising issue. It was felt that meaningful mechanisms should be developed to demonstrate rigorous enforcement of contraventions stemming from advertising. The need for rapid enforcement actions was also raised during discussions. The Working Group also recognized that further work needs to be done to examine whether enforcement activities should be a civil matter as opposed to being under the criminal code.

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Therefore, the Working Group recommends that the Government ensure adequate resources are provided for active monitoring of advertisements, standards, and an identified means for correcting misinformation that reaches the public, and effective sanctions to prevent repeat violations. The issue of adequate enforcement should be addressed as part of the short, medium, and long-term strategies related to Schedule A.



# 1 Issue

The purpose of this report is to provide recommendations on modifications and amendments to, or elimination of, Schedule A and Section 3 of the *Food and Drugs Act*, as reflected in the mandate of the Schedule A Working Group<sup>1</sup>.

## 2 Background

### 2.1 Section 3 and Schedule A of the *Food and Drugs Act*

Section 3 of the *Food and Drugs Act* prohibits the advertising to the general public of any food, drug, cosmetic or device for the treatment, prevention or cure of any of the diseases listed on Schedule A<sup>2</sup> of the *Food and Drugs Act*. This section of the Act also prohibits the sale of a food, drug, cosmetic or device that is labeled in this manner. Section 3 of the Act states:

□.(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.

(3) Except as authorized by regulation, no person shall advertise to the general public any contraceptive device or any drug manufactured, sold or represented for use in the prevention of conception.

1 See section 2.3, Scope of Mandate for Schedule A Working Group  
2 See Appendix II for the listing of conditions

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There are other authorities that relate to the prohibition in Section 3:

Section 30.1(1)(j) of the *Food and Drugs 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.

## 2.2 Section 3 and Schedule A Review Process

In 1993, a Health Protection Branch Regulatory Review was launched to examine the regulations under the *Food and Drugs Act*. The report “A Strategic Direction for Change” recommended that Schedule A be reviewed.

In addition, the House of Commons Standing Committee on Health presented its report on natural health products in November 1998.<sup>3</sup> 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 53 recommendations related to the regulation of natural health products.

On March 26, 1999, the Health Minister announced that he accepted all 53 recommendations of the House of Commons Standing Committee on Health. Two of these recommendations, number 35 and 36 respectively, said that:

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 regulation 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.

3 *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>

In response to these recommendations, Health Canada established an internal Committee with representation from all departmental programs affected by Schedule A, including, food, drugs, medical devices, natural health products and cosmetics. The Committee recommended the following three-phase process:

**Phase I:** the drafting of a guidance document that clarifies the meaning, scope, and current application of section 3 and Schedule A;

**Phase II:** the convening of an External Working Group to review the Schedule A list of diseases and to prepare a report; this report will form the basis for broader public consultations by Health Canada; and

**Phase III:** the long-term process of Legislative Renewal.

To date, the following activities related to phase I and Phase II have been implemented:

- A document entitled *Schedule A and Section 3: Guidance Document* was finalized and posted on Health Canada's website in February 2003.
- On February 14, 2003, Health Canada announced the establishment of the External Working Group.
- On June 9, 2003, the next phase of the Legislative Review Process was announced by the Minister of Health.

### 2.3 Scope of the Mandate for Schedule A Working Group

The mandate of the Schedule A Working Group (WG) is to:

- 1) Review Schedule A list of diseases; 2) Provide recommendation for both short-and long-term processes; and,
- 3) Prepare a report as the basis for broader public consultation by Health Canada. The proposal by the WG may include, but not limited to:
  - criteria that can be used for determining which diseases ought to be included in Schedule A;
  - modification (including addition, removal, renaming, or further clarification of Schedule A diseases) or elimination of Schedule A; and,

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- proposals for certain products or classes of products to be exempted from the application of Section 3 of the *Food and Drugs Act*.

The use of an administrative tool (i.e. regulatory amendment, policy/guideline) to achieve the necessary governing objectives is considered as a short or medium-term proposal. However, the modification of section 3 and/or elimination of Schedule A is

considered as a long-term proposal due to the necessary Parliamentary processes.

Health Canada may consult legal counsels from the Department of Justice, depending on the need, and advise the WG on the legality of the proposals.

## **3 Working Group Process**

The Schedule A External Working Group consisted of representatives from government and regulatory groups, professional associations, consumer/advocacy groups, advertising, media, foods, health products, medical devices etc. Members were nominated by their respective organizations due to their expertise in various areas related to Schedule A. As such, the views expressed in the report are expert opinions of the individual members and do not necessarily reflect the organizations which nominated them. The experiences, perspectives and values that this group brought to the table related to the assigned mandate of this working group were diverse. Early in the process, we acknowledged that addressing the mandate meant navigating the sometimes highly charged socio-political issues that frame healthcare delivery in Canada today. While addressing these issues was outside of the group's focus, we agreed unanimously that they would influence the recommendations being made. We also noted the likelihood that these same issues would come into play during the public consultations phase of this review process. For these reasons, the issues are introduced in Section 4.2 'Current Context' in contrast to the 'Historical Context' presented in section 4.1.

Also, as a means of seeking common ground to work from, and ensuring that decisions respected the broader health needs of Canadians, the Working Group adopted a set of guiding principles. These principles were used to develop options and recommendations as well as help set criteria for determining what diseases should or should not be included in Schedule A.

### **3.1 Guiding Principles**

1. 1. Protect the safety of consumers
2. 2. Optimize health outcomes
3. 3. Improve access to complete, relevant, truthful and validated health information
4. 4. Use evidence-based decision making, which incorporates dynamic and flexible solutions
5. 5. Facilitate responsible self-care and assisted-care decisions, and patient-practitioner discussions

## **4 Issue Analysis**

## 4.1 Historical Context

In assessing Section 3 and Schedule A, it is important to consider the context in which these provisions were introduced into the *Food and Drugs Act* in 1934 and were retained when the Act was revised in 1952 and again in 1953<sup>4</sup>. Life expectancy for Canadians was around 65 years at this time, and the major threats to health were infectious diseases such as polio, tuberculosis and streptococcal infections and trauma. ‘Lay’ information about health and illness was prevalent.

Over time, the following four reasons have been cited as justification for the introduction and continued support of Section 3 and Schedule A:

- 4 The section of the Act referring to Schedule A was introduced as Section 6A in 1934 (C-34). 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) are 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.” *Issue Paper on Schedule A, Legislative Renewal*, Health Canada, July 10, 2003, *Appendix A – Origin of Schedule A*

### 4.1.1 To prevent fraud in advertising and labeling<sup>5</sup>

Radio and newspapers were the primary media influence of the day, as television was a new invention. In the absence of legislative and regulatory controls, the public had little or no protection against false and misleading health claims and advertising of products and medicinal treatment. In addition, there was no requirement for systematic evidence of efficacy to back product health claims at the time the Act was created.

### 4.1.2 To prohibit the advertisement and sale of treatments for conditions where no treatment is known to medical science<sup>6</sup>

When Section 3 and Schedule A were introduced there were no known treatments for some of the conditions listed in the Schedule. In other cases, only symptomatic treatments were available, or available treatments were problematic.

### 4.1.3 To prohibit the advertisement and sale of treatments where self-treatment is not considered safe<sup>7</sup>

In 1934, when Schedule A was introduced, there were fewer restrictions than today on public’s access to products. In the absence of a prescription regime, and without direction or supervision by medical professionals, individuals could freely acquire potent and toxic drugs with potential for misuse and abuse. Requirements for prescriptions to purchase barbiturates, amphetamines and various other drugs did not come into effect until 1941. It was only in 1946, when the *Food and Drugs Act* was further amended, that

there was regulation of antibiotics such as penicillin. These measures were intended to discourage people from the purchase of these potent drugs for self-medication.

5 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.” *Hansard* April 21, 1953

6 R.E. Curran, *Canada's Food and Drug Laws, Commerce Clearing House, Inc.* 1953. p. 188 7 L.I. Pugsley, *Medical Services Journal, Canada*, Vol. XXIII, No. 3, March 1967, pages 387-449

#### 4.1.4 To encourage people to seek medical attention for serious conditions<sup>8</sup>

In the absence of a universal medical-care system, medical-care and consultations with physicians were on a fee for service basis. Individuals who could not afford those fees or who were not inclined to pay for the services, tended to rely on self-diagnosis and treatment. In the absence of an effective regulatory regime, people were also vulnerable to false claims made for cures to various ailments and conditions.

## 4.2 Current Context – Reviewing Section 3 and Schedule A

### 4.2.1 Today's Regulatory Environment

#### *4.2.1.1 Pre-market Review Process*

The modern system of drug regulation was largely introduced following the thalidomide tragedy in 1962. Over the ensuing years, the government has created a regulatory and administrative structure to evaluate the health claims for products. Pre-market review requirements for drugs were introduced following the thalidomide tragedy and pre-market requirements for food additives were introduced in 1964. Foods may only make those health claims that are prescribed in the Regulations based on evidence evaluated by Health Canada. Drugs and natural health products must undergo a pre-market evaluation to obtain a license to sell. Cosmetics may not make health claims as any such claim would result in a re-classification as a drug and require pre-market authorization. Medical devices must also undergo pre-market authorization with the exception of the lowest risk products. However, these products must also comply with the regulations for health claims. The current regulatory system does not allow market access without government regulation of allowable evidence-based claims.

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Some argue that the current regulation of health claims renders Schedule A unnecessary. As noted above most foods and low risk medical devices are not subject to a product-by-product pre-market review. Such products are prohibited from making claims other than those pre-authorized by the Regulations. Some argue that the fact that just because products are subject to pre-market review, it does not ensure that companies will not purposefully or otherwise market a product that does not comply with the regulations. However, Schedule A has no greater effect in this regard and those purposefully marketing outside the legal requirements do so in spite of Schedule A.

Section 2 of the *Food and Drugs Act* defines advertisement 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”. If a message regarding a drug is not considered to promote sale or disposal, it is not subject to the advertising provisions of the *Food and Drugs Act* and Regulations.<sup>9</sup> Moreover, the communication of information for educational purposes is not subject to the *Food and Drugs Act*. It has been a challenge to clearly draw the line between what constitutes promotion for sale and what is the communication of information for educational purposes. However, when the manufacturer of the product produces the educational material, it is more closely reviewed to ensure that the regulations are not contravened.<sup>10</sup>

It is also of interest to note that while Section 3 of the *Food and Drugs Act* prohibits certain products from being advertised to the general public, the term “general public” is not defined in the Act or the Regulations. Instead, it is interpreted within the context of Section 3. For example, health professionals are not considered the general public. Consequently, claims may be approved for professional use only, and manufacturers may distribute promotional material for Schedule A diseases to specified groups such as practitioners.

#### *4.2.1.2. Co-existing Regulations*

It should be noted that there are a number of other provisions in the *Food and Drugs Act* that adequately address fraud, misleading advertising and labeling. For instance, Sections 5, 9 and 20, respectively, of the *Food and Drugs Act*, prohibit the fraudulent promotion or sale of food, drugs and medical devices.

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**Section 5, *Food and Drugs Act***

5. (1) No person shall label, package, treat, process, sell or advertise any food 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.

5. (2) A Food that is not labeled or packaged as required by, or is labeled or packaged contrary to, the regulations shall be deemed to be labeled or packaged contrary to subsection (1)

**Section 9, *Food and Drugs Act***

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.

9. (2) A Drug that is not labeled or packaged as required by, or is labeled or packaged contrary to, the regulations shall be deemed to be labeled or packaged contrary to subsection (1)

**Section 20, *Food and Drugs Act***

20. (1) No person shall label, package, treat, process, sell or advertise any device 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.

20. (2) A Device that is not labeled or packaged as required by, or is labeled or packaged contrary to, the regulations shall be deemed to be labeled or packaged contrary to subsection (1)

Although Sections 5, 9 and 20 may adequately address fraud, these statutory options require government to evaluate products that are marketed in contravention of the law. As the Act and Regulations evolved from the time of the introduction of Schedule A, there has been a shift in approach that requires government oversight of all products making health claims. This takes place either through a product-by-product review for drugs, natural health products and most devices to statutory restrictions on specific pre-authorized claims on foods and low risk devices. Therefore, any product making an unauthorized health claim would, by definition, not be in compliance with regulations. The current system has as its compliance tool a straight-forward solution to ensure claims



are valid by removing products that do not comply with the provisions of the Act. Sub-section 2 of these provisions state that “no person shall sell” a product unless labeled according to the regulations.

In addition to the federal government’s evaluation of health claims there are other Federal Acts (e.g. the Competition Act and the Consumer Packaging and Labeling Act) and Provincial Acts (e.g. the Ontario Business Practices Act) as well as their regulations that govern product claims.

### **Criminal Code**

Section 408 of the Criminal Code describes a number of offences similar to those described in Sections 5, 9 and 20 of the *Food and Drugs Act*:

408. Every one commits an offence who, with intent to deceive or defraud the public or any person, whether ascertained or not,

a) passes off wares or services as and for those ordered or required;

b) makes use, in association with wares or services, of any description that is false in a material respect regarding

I) the kind, quality, quantity or composition,

II) the geographical origin, or

III) the mode of manufacture, production or performance of those wares or services.

Whereas Section 5, 9 and 20 refer to offences as “label, package, treat, process, sell or advertise food, drug or device, in a manner that is false, misleading or offensive, the Criminal Code describes the offences in general terms as ”passing off” wares or services, which cover among other things foods, drugs, devices and cosmetics.

The *Food and Drugs Act* is part of the criminal law in Canada. It has jurisdiction throughout the country unlike Agriculture, Fisheries and related statutes that require a regulated commodity to move inter-provincially or internationally before the law becomes operative. Although the domain of ‘health’ is constitutionally under provincial jurisdiction, having the Food and Drug Act as part of the criminal law permits the federal government to enter the health domain on a constitutionally valid basis and to implement regulations and health and safety standards which are enforceable throughout the country.

Enforcement of regulations under the *Food and Drugs Act* can be more difficult because the *Food and Drug Act* is part of the criminal law and laying charges for a violation requires the Crown to prove the charges ‘beyond a reasonable doubt’. This is unlike being charged under legislation that does not fall under criminal law where the

‘weight of the evidence’ is the standard that is used.

### **Canadian Code of Advertising Standards**<sup>11</sup>

The *Canadian Code of Advertising Standards* (Code) was first published in 1963 to promote the professional practice of advertising. Since that time it has been reviewed and revised periodically to keep it contemporary. The Code is administered by Advertising Standards Canada/Les normes canadiennes de la publicité (ASC). ASC is the industry body committed to creating and maintaining community confidence in advertising. This voluntary system of pre-clearance is supported by the compliance and enforcement powers of Health Canada. The ongoing effectiveness of the voluntary pre-clearance system is monitored by Health Canada whose officials are members of the various Sector Advertising Boards of ASC.

<sup>11</sup> See Appendix VI for details

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The Code sets the criteria for acceptable advertising and forms the basis upon which advertising is evaluated in response to consumer, trade, or special interest group complaints. It is widely endorsed by advertisers, advertising agencies, media that exhibit advertising, and suppliers to the advertising process. In addition to the overall standards, ASC administers the sector-specific guidelines for advertising. There are specific guidelines for foods as well as self-care products.

Consumer complaints to ASC about advertising that allegedly does not comply with the Code are reviewed and adjudicated by the English national and regional Consumer Response Councils and by their counterpart in Montreal, le Conseil des normes (collectively referred to as Councils and individually as a Council). These autonomous bodies of senior industry and public representatives are supported and coordinated by, but altogether independent from, ASC.

Trade complaints about advertising, based on the Code, are separately administered under ASC’s Trade Dispute Procedure. Complaints about advertising from special interest groups are separately administered under ASC’s *Special Interest Group Complaint Procedure*.

## Considerations for Advertising of Prescription Products

While Direct-Consumer-Advertising (DTCA) of prescription drugs was not within the mandate of the Working Group, and is dealt with separately within Health Canada's Legislative Renewal Process, some members felt that since Canadians are already exposed to advertising for Schedule A diseases via the spill into Canada of U.S.-based advertising, this reality has some bearing on the discussion.

With a prescription regime now in place, drugs are used under the direction and supervision and monitoring of health care professionals who help to ensure the safe use of drugs. Statutory authority supplements this supervision. For example, Section C.01.041 of the *Food and Drugs Regulations* requires chemical entities or classes of drugs listed in Schedule F to be sold under prescription<sup>12</sup>. In addition, Section C.01.044 of the *Food and Drugs Regulations* restricts the advertising of prescription drugs to the general public:

<sup>12</sup> See Appendix III

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.*

Promotional claims for Schedule A diseases or conditions reach Canadians every day through the direct to consumer advertising (DTCA) for prescription drugs in the United States via U.S.-based magazines, newspapers and television programming, and through the internet. The spill of these advertisements from the United States into Canada is so great that the majority (57% Ipsos-Reid Oct 2003) of Canadians believe that Canada already allows this kind of advertising. While Health Canada has jurisdiction over advertising originating in Canada, it has no enforcement powers over advertising and sales originating from outside of Canada, unless such advertising is specifically intended for a Canadian audience.

In Canada, where advertising of prescription drugs is permitted to health professionals, it is the Pharmaceutical Advertising Advisory Board (PAAB) that acts as an independent review agency. Its primary role is to ensure that advertising of prescription drugs to professionals is accurate, balanced and evidence-based. The Therapeutic Products Directorate, Health Canada, is an ex-officio observer to the Board of Directors. The Directorate acts as advisor to the Board, without relinquishing any part of its authority under the Food and Drugs Act and Regulations.

A common theme often surfacing during discussions around DTCA was the importance of public's access to education in cases of new diseases and new treatments.

Many members viewed education as an important compliment to advertising of health products. They emphasized the need for effective funding mechanisms to support educational programs. A strong post-market surveillance program is a critical element for assessing the impact on patients of health products for ensuring safety and effectiveness.

It was also recognized that concerns about DTCA in the drug market are not easily applied to advertising of food, self-care products and low-risk devices, as the markets for these products are consumer driven.

While some members supported continuing and extending current advertising prohibitions, some had concerns about the existing regime and its likely incompatibility with the Charter of Rights and Freedoms.

#### *4.2.1.3 Compliance and Enforcement*

It is clear that enforcement of any regulations that are put in place is critical. In order for Canadians to have confidence in the advertising regarding health claims, they must also have confidence that the regulations governing evaluation of safety and efficacy and content of advertisements are being monitored and enforced. This would include adequately resourced enforcement procedures with active monitoring, standards, and an identified means for correcting misinformation that reaches the public, and effective sanctions to prevent repeat violations.

The Working Group recognized that the recommendations in this report increase the potential for advertising with a substantial impact on the overall advertising for health products. With this recognition, while the members unanimously underscored the critical importance of increased public education on risks and benefits of health products, they noted that enforcement must be targeted at this overarching advertising issue. It was felt that sufficient and dedicated resources are needed to support meaningful enforcement of contraventions stemming from advertising. These could include government regulation as well as self regulation. The Working Group was aware of the pressures related to scarce public resources and competing priorities which may hinder enforcement measures. Some potential enforcement mechanisms discussed by the Working Group include:

- pre-market clearance (requirements for licenses to advertise);
- post-market surveillance (voluntary or government monitoring);
- adequate penalties (monetary penalties, “corrective advertising” to address violations in advertising);

The need for rapid enforcement actions was also raised during discussions. The WG also recognized that further work needs to be done to examine whether enforcement activities should be a civil matter as well as, or instead of, falling under the criminal code.

#### **4.2.2 Shifting Healthcare Paradigm**

#### *4.2.2.1 Attitudes about health and healing*

The Working Group discussed how societal attitudes about health and healing and public expectations surrounding cost and access have shifted considerably over the years. Canadians now have access to a universal health-care system, are better educated, and know they can seek medical assistance regardless of their income level or ability to pay. While the current trend is towards being actively involved in the type of treatment they receive, there are significant individual differences in the type of support and level of direction a patient may seek for their health concerns.

The federal government plays a major role in protecting and promoting public health through regulatory and policy directions. The increased focus on health promotion in recent years reflects society's move towards a preference for a participative approach to healthcare delivery. This has been a factor influencing the legislative renewal process and the mandate of this working group.

Despite the paradigm shift towards self-care, holisms and patient-as-partner, the Working Group acknowledges the necessity for medical diagnosis, treatment and monitoring of serious diseases.

#### *4.2.2.2 Chronic Illness as an Emerging Issue*

As North America's population ages, the prevalence of chronic illness in our society has increased concurrently. People are living longer with diseases that at one time would have led to serious disability and/or early death. Some predict that the cost of healthcare related to the management of chronic illness will be the greatest economic burden Canadians face in the years ahead. This issue is relevant in the Schedule A discussion, as it links to the argument for early intervention and cost-efficient self-care and improving the public's access to health products, food and devices that can help.

At one time, 'treatment of illness' related specifically to the concept of cure or the eradication of the condition. Today, improved quality of life is recognized as a primary goal for many people living with chronic illness.

#### *4.2.2.3 Complementary and Alternative Health Care*

Over the past decade, there has also been increasing interest in complementary and alternative health care (CAHC) – practices, products and therapies. In a 1999 survey, nearly half of all Canadians indicate they have used some form of CAHC<sup>13</sup>. The literature suggests a number of possible reasons for this trend which include: a perception that CAHC is a more 'natural', less invasive and less expensive approach to health; access to an expanded 'toolbox' of healing approaches, particularly for people living with chronic illness for which Western medicine offers no cure and limited relief of symptoms; a more

collaborative, less paternalistic relationship between patient and practitioner. *Perspectives on Complementary and Alternative Health Care: a collection of papers prepared for Health Canada* (2001). Health Human Resource Strategies Division, Health Canada.

Ramsay, C., Walker, M. & Alexander, J., 1999. Alternative medicine in Canada: Use and public attitudes. *Public Policy Sources*, 21, Fraser Institute.<sup>14</sup> The greatest challenge related to this trend that the public faces is timely access to evidence-based product claims to assist in their health decision-making. There has been a concurrent increase in research activity in the field as evidenced by the number of new peer-reviewed journals focused on CAHC and integrative medicine which has sprung up over the past six years. Federal initiatives such as the Natural Health Products Directorate (Health Canada) and National Center for Complementary and Alternative Medicine (National Institutes of Health, USA) provide structure and agendas for much of this work.

13 Angus Reid Group Inc., 1998. *Use and danger of alternative medicines and practice: Parts I and II*. Consumer poll conducted by CTV/ Angus Reid Group Poll in August 1997

14 *Perspectives on Complementary and Alternative Health Care: a collection of papers prepared for Health Canada* (2001). Health Human Resource Strategies Division, Health Canada Ramsay C., Walmer, M. & Aleander, J., 1999. *Alternative medicine in Canada: Use and public attitudes*. *Public Policy Sources*, 21, Fraser Institute.

#### ***4.2.2.4 Vulnerability of Patient Populations***

The idea that mental incapacity, poverty, serious illness, pain, disability and fear of future illness, and death leave patients and their families/caregivers especially vulnerable to false claims, has not changed since the Act was introduced in 1934. Some members of the Working Group argued for restricted claims for mental illness, cancer and HIV/AIDS, in an attempt to address the risk to vulnerable populations. Others made the assumption that at some point in our lives, most human beings will be part of a 'vulnerable population'. In addition, the Working Group felt that it was necessary to consider the implication of restriction of product claims for the use of caregivers to the vulnerable populations. There was consensus among the group that ongoing vigilance, such as consumer-oriented post marketing surveillance, is both necessary and inevitable in today's health-care environment.

#### ***4.2.2.5 Information, mass media and the role of healthcare charities/ non-***

### *profit consumer advocacy groups*

Public access to the nearly unlimited health information available today has its pros and cons. On one hand, resources to support responsible self-care are far more available today than in 1953. On the other hand, consumers are often overwhelmed by the sheer volume of information sources and may be unable to distinguish credible research results from false claims. Healthcare professionals are overwhelmed for the same reasons, and additionally challenged to find the time to review and discuss all of the information their patients bring to them.

Canada's media industries – broadcasting, magazines, newspapers and the Internet also have increasing potential to shape the health decisions people make. 89% of Canadians read a magazine each month, newspapers reach 66% of adults over 18 and on average Canadians watch 25.1 hours of television a week.

As media exposure to Canadians grows, so does the potential influence of advertising and health information, on our health behaviors.<sup>15</sup>

15 See Appendix VII

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In today's society, there are an ever-increasing number of non-profit organizations that identify 'education' of their constituents as part of their mission by becoming brokers of credible information. Many have taken on the daunting task of vetting available information for the people they serve. In doing so, they attempt to meet a very large consumer need that is not routinely addressed by industry or by healthcare providers. That is the exchange of clear, unbiased information that presents the risks and benefits of using a particular food, product or device. Patient-centered post-market surveillance is another activity many organizations and their constituents are advocating for. Programs that collect and disseminate ongoing data about adverse reactions as well as positive patient outcomes have the potential to serve as major educational tools for specialized consumer groups.

## 5 Summary of Issues

Working Group members identified the following areas to be relevant to their mandate when developing recommendations.

- With advances in health care, treatment for many of the diseases listed in Schedule A is now available. Though there is still no known cure for many of the diseases listed in Schedule A, such as arthritis and diabetes, modern therapies allow these chronic conditions to be successfully managed. For example, a product could lessen discomfort caused by a condition or slow the progression of a disease. In addition, with the potential of new groups of products such as those stemming from gene therapy, treatments may soon be available for diseases that are not currently treatable.
- Despite the paradigm shift towards self-care, holisms and patient-as-partner – there is still an important role for the medical diagnosis, treatment and monitoring of serious diseases.<sup>16</sup>
- Over the years, co-existing regulations, both in law (Schedule F; Sections 5, 9 and 20) and through voluntary industry codes (Advertising Standards Canada etc.), have been developed against fraud in labeling and advertising and sale of treatments. In addition, the current pre-market review system only allows evidence-based

<sup>16</sup> Guiding principles #1, #2, #5

health claims on foods, and medical devices. Health products such as pharmaceuticals and natural health products must undergo a pre-market evaluation to obtain a license to sell.

- The enforcement of existing or amended regulations would require a significant and ongoing investment of resources.

## 6 Considerations

Over the course of nine months, the External Working Group met 6 times, engaged in a number teleconferences as subgroups, and reviewed various analytical and research pieces to support its recommendations on modifications to Section 3 and Schedule A provisions as recommended by the House of Commons Standing Committee on Health in 1998.

As evidenced in the analysis section of this report, the issues before the members were complex and encouraged much debate where views differed, particularly when differences arose due to broader philosophical perspectives. The challenge at times was to manage the process as to keep the deliberations within the mandate of the Working Group. Towards the end of the process, when the group was engaged in formulating its recommendations, it became clear that while many of the members came to a consensus on a number of proposed options, a few members expressed different opinions. As such,



this report reflects the views of the Working Group, where there was consensus and where there were opposing views.

The following recommendations are based on the analysis of the historical and the current Canadian context as well as the international comparisons found in the appendices to this report<sup>17</sup>.

17 Appendices VIII & IX – International Comparisons

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## 7 Recommendations

Consistent with the Standing Committee on Health recommendations 35<sup>18</sup>, 36<sup>19</sup>, and the 1993 Health Protection Branch Regulatory Review, “*A strategic Direction for Change*”, the members of the External Working Group unanimously agreed that Section 3 and Schedule A needed to be amended. However, there was a difference of opinion as to the best manner to make such changes.

### Summary of discussions

In assessing various options, Working Group members unanimously agreed that, *Amendments to Section 3 and Schedule A should maintain and promote public health as the primary objective.*

The group recognized that the regulatory system in place today is a far different and more comprehensive system than what was in place at the time Schedule A was introduced. Today’s system has more checks and balances to prevent fraud than nearly half a century ago when Schedule A was the primary tool to protect consumers from dangerous or misleading claims<sup>20</sup>. The group also recognized that the Schedule A prohibitions had no bearing on the ability of prescription drugs to advertise and so the list of diseases impacts lower-risk products such as foods and self-care products<sup>21</sup>.

- 18 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 regulation from the broad terms found in Schedule
- 19 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.
- 20 According to Section 5, 9 and 20 of the *Food and Drugs Act*, “No person shall label, package, treat, process, sell or advertise any [foods/drugs/medical devices] in a manner that is false, misleading or deceptive...” therefore such advertising, including scientifically supported health claims, cannot be false or misleading. See section 4.2.1
- 21 Section C.01.041 of the Food and Drugs Regulations requires Schedule F drugs to be sold under prescription.

Most members also agreed that health products which provide a benefit against Schedule A disease states (e.g., structure/function, or risk reduction) should clearly communicate these benefits to consumers provided that the sponsor offers sufficient scientific support of the claims. With the increasing cost of health care in Canada and the growing public awareness for health issues, consumers should be provided full information on the benefits of the products to make informed decisions regarding their own health. The limitation imposed by Schedule A to providing clear indication of use on product labels impedes this process greatly<sup>22</sup>. Some members were concerned about the ability of brand-specific prescription drug advertising to provide balanced information about health products, and would prefer unbiased information dissemination in place of advertising. A few members, however, were opposed to removing any advertising prohibitions on any product making health claims.

The fundamental question debated was whether or not a manufacturer that has provided Health Canada with adequate evidence of his or her product’s effectiveness in preventing, treating or curing a disease, should be prohibited by law from advertising that product to the public. Guiding the Working Group’s thinking was the clearly articulated objective of Health Canada to empower Canadians to make informed health choices and providing them with timely access to safe and effective products that are of high quality. Many of the members were also concerned over any legislative or regulatory requirements that were actually outright prohibitions without adequate evidence of a need to take such measures when other evidence-based measures adequately protect the public.

The Working Group explored potential short-term recommendations that would not involve any regulatory or legislative changes, medium-term recommendations involving regulatory but not legislative changes, and longer-term recommendations that might include broader legislative change.

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In the final analysis, most members recommended phased-in modifications to Schedule A and Section 3 in the short and medium-term with the ultimate goal of legislative amendments to the Act, while a few opposed any changes to the current legislation. The proposed long-term options, take into account Health Canada's proposed new Canada Health Protection Act including options for legislative amendments to Section 3 and Schedule A. The administrative and regulatory changes recommended are with a view to improving the efficacy of the current system by various degrees in the short and medium-term, through the various authorities stated below.

Administrative changes can be addressed through revisions to the compliance guidance document by Health Canada. Legislative amendments to Section 3 and Schedule A are being addressed through Health Canada's broader proposal for a new Canada Health Protection Act and the public consultation process currently underway. Sections 30.(1)(j) and 30.(1)(m) of the Food and Drug Act allow for regulatory changes:

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.

## Overview of Recommendations

Given their mandate, the External Working Group recommends short-and medium-term modifications to Schedule A for direct public consultation. Legislative options are to be considered during Health Canada's legislative renewal public consultations. The Working Group recommends:

1. 1. In the short term revise Health Canada's 'Guidance Document on Section 3 and Schedule A to include definitions for terms used in Section 3 that are not provided for in the Act.
2. 2. In the medium term proceed with regulatory amendments to Schedule A

according to Section 30. (1)(m), and modify the list of diseases in Schedule A to reflect the current context.

- .3. In the long term support the following legislative options:
  - Option 1: Complete Elimination of Section 3 and Schedule A
  - Option 2: Elimination of Schedule A and Amending Section 3
- 3. 4. Ensuring Adequate Resources for Enforcement

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Many of the members support these changes while a few have expressed different opinions in a number of areas. Where there have been differences, both views are presented in the following sections.

### **7.1 Recommendation 1 — Short-term Administrative Amendments: Revise Health Canada’s ‘Guidance Document on Section 3 and Schedule A**

The terms “Treatment”, “Preventative”, and “Cure” are not defined in the Act or Regulations. However, these terms can be defined in a transparent manner in Health Canada’s *Guidance Document on Section 3 and Schedule A*. Drafters of the original legislation did not document Parliament’s intent when the terms were introduced into the Act and, as such, left for interpretation when product claims are being reviewed by Health Canada.

The External Working Group recommends that in the short term, Health Canada to revise the compliance guidance document to include:

- Definitions of “Treatment”, “Preventative”, and “Cure”, “Symptomatic Treatment” and “Risk Reduction” to clarify distinction between product claims that are prohibited and those that are allowed. Definitions should clearly demonstrate that preventive, cure and treatment claims are not allowed. It was proposed that the concepts of “Risk Reduction” and “Symptomatic Treatment” be introduced to further clarify the terms.
- Clarifications of disease nomenclature in Schedule A.

#### *Overview of Health Canada’s Guidance Document on Section 3 and Schedule A*

#### *Current Status*<sup>23</sup>

Section 3 prohibits claims of “prevention”, “treatment” or “cure” for any of the conditions listed in Schedule A. Health Canada has created a policy to aid in their compliance activities for Schedule A. The current policy interpretation elaborates the prohibition in the Act to include other claims. The following are listed in the guidance

document<sup>24</sup> as examples:

- “This product may assist in the management of disease X”;
- “This product may be used as an adjunct in the treatment of disease X”;
- “This product may help reduce the risk of disease X”.

23 The full document can be found at: [http://www.hc-sc.gc.ca/hpfb-dgpsa/sched\\_a\\_gui\\_doc\\_cp\\_e.html](http://www.hc-sc.gc.ca/hpfb-dgpsa/sched_a_gui_doc_cp_e.html) 24 Guidance document p. 4, para 3

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A claim to treat, prevent or cure, signs or symptoms of a Schedule A disease is also deemed prohibited as it “...is considered to be a claim to treat, prevent, or cure the disease itself”.<sup>25</sup> However, claims for products designed to relieve the pain associated with arthritis such as “for the relief of pain due to or associated with arthritis” have been allowed historically, as the treatment of “pain” is not considered to be a claim to treat the disease. Interpretation of whether a claim is allowed or not varies with the level of prominence given to the relief of pain statements and to any reference to the disease itself. The claim would be prohibited if it implies that the arthritic condition itself will be relieved or that the functioning of the articulations will be improved.<sup>26</sup>

The guidance document currently allows for claims to control a risk factor for a Schedule A disease state provided the disease itself is not mentioned. For example, claims such as “this product helps maintain healthy cholesterol levels” or this product does not raise blood sugar levels” may not necessarily relate to arteriosclerosis and diabetes respectively, and would not be prohibited.<sup>27</sup>

### *Recommended changes to the Guidance Document on Section 3 and Schedule A*

Members discussed the implication of revisions to the guidance document in the following four areas:

1. 1. Process and rationale for revising guidance document;
2. 2. Clarification of “advertising”, “information” and other concepts;
3. 3. Definitions of “treatment, prevention or cure”;
4. 4. Definition of disease states.

25	Guidance	document,	p.5
26	Guidance	document,	p.5
27	Guidance	document,	p.5

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#### **1. Process and rationale for revising guidance document**

Most members supported revisions to the guidance document recognizing that these changes are administrative in nature and do not need to go through a legislative or regulatory review process. However, these members recognize the need for public consultation prior to finalizing the guidance document. A few members, however, were of the opinion that revisions to Health Canada’s guidance document should not be undertaken.

## **2. Concept of “advertising” vs. “information”**

It was agreed that some terms used in Section 3 and Schedule A should be clearly defined to ensure that the original intent of Schedule A is fulfilled. While it was noted that advertising is intended to “sell” a product, some members expressed concern around how definitions could ensure that consumers receive truthful advertising of approved claims while ensuring that the regulations do not impede the provision of accurate and unbiased information to consumers.

There was discussion as to whether it was the intent of Section 3 to prohibit communication of claims by other means e.g. labels. Section 3 (2) of the Act clearly states:

- (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, preventive or cure for any of the diseases, disorders or abnormal physical states referred to in Schedule A.<sup>28</sup>

Schedule A prohibits Health Canada from approving a claim for a product used by consumers for self-care. Examples of claims that have been evaluated by Health Canada, but are prevented from being labeled for advertising because of Schedule A, are found in Appendix X.

<sup>28</sup> See Section 2.1

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Some Working Group members are of the view that further exploration of the concepts of “advertising” and “information” is needed to see if a distinction might be made in law or in the guidance document. Definitions discussed by the Working Group follow:

Figure 1 - Definitions discussed by the Working Group

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.<sup>129</sup>

**Advertisement**

Direct-to-Consumer Advertising has the same meaning as advertising

**Direct-to-Consumer**

but the scope is limited to consumers only, and not health care

**Advertising**

professionals. The term Direct-to-Consumer Advertising is used with prescription drugs specifically.

Includes any legend, word or mark attached to, included in, belonging

**Label**

to or accompanying any food, drug, cosmetic, device or package.<sup>230</sup>

Information /activities not intended to promote the sale of a drug, but for educational, professional or scientific purposes only. Where it is unclear to determine whether the purpose of the message is to promote the sale of a drug or to provide information, the following seven factors would need to be considered: <sup>331</sup>

1. Context in which the message is disseminated

**Information**

1. 2. Primary and secondary audiences
2. 3. Provider of the message
3. 4. Sponsor of the message and approach used
4. 5. Influence of a drug manufacturer on the message content
5. 6. Content of the message
6. 7. Frequency of the message delivered

**3. Definitions of “treatment,” “preventive” “risk-reduction” and “cure”**

While many members agreed to the definitions set out below, others expressed different opinions. Their views on specific definitions are stated along with those

proposed by the majority of the members.

29	1	See	Appendix	I,
30	2	See	Appendix	I
31	3	See	Appendix	IV

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**Treatment:** should be defined as “*A product administered for the purpose of improving the underlying disease state or condition*”. This definition excludes claims for **Symptomatic Treatment** that is defined as “*A product that relieves symptoms without resolving the underlying disease or condition*”.

A few members’ position was that **Symptomatic Treatment** should continue to be subsumed in the definition of **Treatment**, above. They argued that the limited definition of ‘treatment’ is not consistent with the regulator’s initial intent, past application of the law, nor the general public’s understanding of the terms. However, as stated in *Schedule A and Section 3: Guidance Document*, claims for relief of symptoms such as pain, are already allowed by Health Canada.<sup>32</sup>

**Preventative:** should be defined as “*A product designed to absolutely (100%) avoid the occurrence of disease or condition.*” This definition implies that no claim of prevention should be allowed for any product for any Schedule A disease state as this would be misleading to the public and offer a false sense of security. This interpretation would separate the term “risk reduction” from “prevention”.

**Risk Reduction:** would be defined as “*A product used to control factors associated with the onset of a disease or condition; or used to decrease the likelihood of developing a specific disease or condition itself.*” This interpretation would allow for health products to make risk reduction claims for Schedule A disease states, provided there is evidence to support such claims.<sup>33</sup>

A few members were of the opinion that “prevention” and “risk reduction” are indistinguishable, and “risk reduction” should be subsumed in the definition of “prevention”. They felt that unless properly controlled, risk reduction claims could be interpreted as full prevention claims by consumers, and therefore contravene the intent of the regulations.

The Working Group recognized that re-defining these terms would change the existing Health Canada interpretation of Section 3 of the Act. In doing so, it is important that the compliance guideline sets out parameters to ensure that claims of risk reduction are not communicated in a way that consumers would be led to believe that the products will prevent a disease from occurring in every individual.



**Cure:** Should be defined as “*A product to end a disease or condition.*”

The working Group has reached consensus on the above definition of “cure”.

<sup>32</sup> See reference to relief of pain associated with arthritis in *Overview of Health Canada’s Guidance Document on Section 3 and Schedule A: Current Status*, Section 7.1, p. 24

<sup>33</sup> See appendix X.

#### **4. Definition of Disease States**

Members agreed that there is a need to provide greater clarity around the scope of disease states in the current Schedule A. For example, “Disease of the prostate” is currently interpreted to prevent claims against urinary incontinence, regardless if the product is for a man or a woman. The compliance guidelines should be revised through a consultative process to ensure such extrapolations of disease definitions are not inappropriately applied.

#### **7.2 Recommendation 2 – Medium-Term Regulatory Amendments to Schedule A<sup>34</sup>**

As with the short-term recommendation, while the majority of the Working Group support the following recommended amendments to Schedule A, a few members have expressed different opinions. These members raised concerns around advertising on products making health claims.

The External Working Group recommends the following modifications to Schedule A:

- Replace the current Schedule A with a shorter list of diseases;
- Establish a set of criteria for review of Schedule A diseases.

In an effort to introduce consistency in decision-making, the group set out to develop a list of criteria against which diseases could be evaluated in order to test the need to impose limitations on advertising for prevention, treatment or cure of diseases.

The group recognized that developing such criteria, when effective lower-risk products exist, creates a basic dilemma. Given the current regulatory system that prescribes the conditions under which a product is sold, a product may only advertise for

any claim if it has been granted authorization to label and sell. On the other hand, if evidence for a product was presented that supported the claim for a disease on Schedule A, provisions in Section 3 would force a withholding of a manufacturer's right to label and advertise their product for the listed disease.

<sup>34</sup> See Appendix IX for Case Studies

It was argued that under a regulatory system that adequately addresses product safety, quality and efficacy, there is no need to have a list of prohibited diseases. The regulations permit only marketing products with pre-authorized claims and restrict advertising of products. The mandate of the legislation is restricted to product regulation rather than disease regulation. In addition, the group had difficulty finding criteria that could fully withstand the challenge of the following question: If a product has adequate evidence to support a claim for any disease and the product itself is not of sufficient risk to make it a prescription drug, why should Canadians be prevented from being told of the products availability for such a claim by the manufacturer?

Most members felt that the real solution lies in a legislative change to correct the fundamental problem with the current law. Some argued that Schedule A should be emptied of all diseases. On the other hand, the Working Group was advised that it would not be acceptable to have a schedule that is referenced in the Act and that was empty. The group noted the dilemma arising from the contradiction in obligation to have some diseases in a list that should not necessarily exist under the current regulatory system.

After setting out several initial criteria, most members finalized four criteria for reviewing Schedule A:

1. 1. The disease state results in a serious public health risk and is likely to lead to the spread of the disease without appropriate treatment.
2. 2. The disease requires emergency care where self-care is inappropriate
3. 3. The severity of the disease limits the person's ability to make health decisions
4. 4. The disease state is new and still under investigation

Others were of the view that adding the following criteria to the above would improve the government's ability to prohibit product-specific advertising on public health grounds:

- The disease or condition is one which renders individuals especially vulnerable to harm from unnecessary exposure to drugs and other health care products

Some concerns were expressed with all of these criteria. For example, in-home defibrillation devices are now available and do not require interventions but are certainly emergency treatment for a Schedule A disease (heart disease).

The group also discussed whether it was reasonable to ban advertising that caregivers could use to help those with limited ability to make decisions on their own. Finally, it would be an unlikely circumstance where an emerging disease is treatable by an approved self-care product, food or device.

In spite of the concerns, the group did review schedule A using these criteria and found that most diseases would not likely meet these criteria. As a result of the review, nine out of forty diseases would likely remain in the list.

In fulfilling its mandate and based upon the application of criteria listed above, the Working Group developed an initial list of diseases for inclusion in Schedule A. As a result of this exercise, the diseases listed below emerged. While the Working Group fully supports this list, it anticipates further reviews by experts in the fields of diseases, Health Canada, and through public consultations. The Working Group further recommends that these reviews be based upon the criteria developed by the group.

- |                 |  |
|-----------------|--|
| 1. Alcoholism   | 6. Impetigo                                  |
| 2. Appendicitis | 7. Cancer (except for the reduction of risk) |
| 3. Dysentery    | 8. Strangulated Hernia                       |
| 4. Epilepsy     | 9. Glaucoma                                  |
| 5. Gangrene     |  |

The majority also recommends that owing to the extensive consultation which has and will take place outside the *Canada Gazette* process, the comment period associated with the Gazette process be kept to the minimum required.

### **7.3 Recommendation 3 — Long-Term Legislative Changes to Section 3 and Schedule A**

In developing its long-term recommendations, the External Working Group reviewed the legislative options for modifications to Section 3 and Schedule A laid out in Health Canada's Legislative Renewal Proposal for a new Canada Health Protection Act, currently under public consultation. While many agreed to the proposed recommended options set out below, others expressed opposition to the replacement of the *Food and Drugs Act* with a new Health Protection Act.

For amendments through legislative change, the Working Group recommended maintaining certain controls on advertising through regulation with some flexibility so that certain types of claims are allowed; and that the ability to advertise for certain diseases be established through regulation and maintained according to sound evidence-based principles.

In both options, it was felt a mechanism should be in place that assesses the impact of a product's appropriate use and broader implications.

### ***Option 1: Complete Elimination of Section 3 and Schedule A***

As previously mentioned, most members felt that section 5, 9 and 20 of the current *Food and Drugs Act* is sufficiently broad to capture the criteria outlined in the medium-term recommendations. These sections are themselves a prohibition with much broader application than Section 3. Sections 5, 9 and 20 would cover all advertising, to both the public and health professionals, for any disease or condition. These sections were written into the Act much later after Section 3 and therefore reflect the general need to prohibit false advertising to any member of society.

Whereas these sections do not prescribe the prohibited diseases, the Act does give the Governor in Council the authority to write regulations: “(b) respecting (i) the labelling and packaging and the offering, exposing and advertising for sale of food, drugs, cosmetics and devices,” Consequently the ability to manage the conditions of advertising for specific types of health products more aptly resides with the particular regulatory authority within the Minister’s portfolio. The result would be greater flexibility in determining which diseases should carry advertising restrictions related to particular products. It would also provide for risk-management decisions that would allow advertising where there is clear evidence of benefits obtained from the use of the particular health product.

This option further recommends that no such legislative prohibition be put into the proposed Canadian Health Protection Act preventing the sale of a product for any disease state. Rather, a provision giving the Governor in Council the authority to prescribe conditions of advertising similar to what is mentioned above should be included.

This recommendation is consistent with current Government of Canada risk management regulatory frameworks that allow evidence-based decision-making by the regulator to determine whether a product is appropriate for advertising to the general public. The mechanism for determining suitability of advertising will vary from one regulatory authority to the next. A single approach is inappropriate because of the relative risk different products represent.

### ***Option 2: Elimination of Schedule A and Amending Section 3***

This option proposes that Schedule A be removed and Section 3 of the Act be amended to establish controls on advertising to any member of the general public for products covered by the Act, to diagnose, prevent, treat or cure a disease/condition. The legislation would give authority to the Minister or Governor in Council to determine the disease/condition for which the particular regulated health product could not be advertised to the general public. The diseases/conditions would be determined according to a set of principles established in legislation (Section 3).

These principles would be consistent with the criteria the working group put forward in the medium-term recommendations.

1. 1. The disease state results in a serious public health risk and is likely to lead to the spread of the disease without appropriate treatment.
2. 2. The disease emergency care where self care is inappropriate
3. 3. The severity of the disease limits the person's ability to make health decisions
4. 4. The disease state is new and still under investigation

#### **7.5 Recommendation 4 — Ensuring Adequate Resources for Enforcement**

The Working Group recognized that the recommendations in this report would relax current restrictions on advertising of health claims and could lead to a substantial increase in the overall advertising of health products. All members were of the view that enforcement of any regulations that are put in place is critical. In order for Canadians to have confidence in the advertising regarding health claims, they must also have confidence that the regulations governing evaluation of safety and efficacy and content of advertisements are being monitored and enforced.

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The Working Group recommends that under the existing or amended regulations, the government should include adequately resourced enforcement procedures with active monitoring, standards, and an identified means for correcting misinformation that reaches the public, and effective sanctions to prevent repeat violations. The issue of adequate enforcement should be addressed as part of the short, medium, and long-term strategies related to Schedule A.

Enforcement could include both government regulation and self regulation. Some potential enforcement mechanisms which the Working Group discussed include:

- Pre-market clearance (e.g. requiring a “license to advertise”);
- Post-market surveillance (voluntary or through government monitoring);
- Adequate penalties (monetary penalties, “corrective advertising” to address violations in advertising);

The need for rapid enforcement was also discussed. In addition, the Working Group suggested that further work be done to examine whether enforcement should be a civil matter as well as, or instead of, falling under the criminal code.

The Working Group acknowledged that scarce public resources and competing priorities may hinder enforcement measures. However, they believed that due to the need, dedicated resources for enforcement should be found.

## Appendices

# Report of the External Working Group on Section 3 and Schedule A

## APPENDIX I Definitions and Glossary of Terms

### Definitions

The following, except as otherwise indicated, are taken from the *Food and Drugs Act* or Regulations.

**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;

**Cosmetic:** includes any substance or mixture of substances manufactured, sold or represented for use in cleansing, improving or altering the complexion, skin, hair or teeth, and includes deodorants and perfumes;

**Device:** means any article, instrument, apparatus or contrivance, including any component, part or accessory thereof, manufactured, sold or represented for use in

- . • the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or animals,
- . • restoring, correcting or modifying a body function or the body structure of human beings or animals,
- . • the diagnosis of pregnancy in human beings or animals, or
- . • the care of human beings or animals during pregnancy and at and after birth of the offspring, including care of the offspring,

and includes a contraceptive device but does not include a drug;

**Drug:** includes any substance or mixture of substances manufactured, sold or represented for use in

1. 1. the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or animals,
2. 2. restoring, correcting or modifying organic functions in human beings or animals, or
3. 3. disinfection in premises in which food is manufactured, prepared or kept;

**Food:** includes any article manufactured, sold or represented for use as food or drink for human beings, chewing gum, and any ingredient that may be mixed with food for any purpose whatever;

**Label:** includes any legend, word or mark attached to, included in, belonging to or accompanying any food, drug, cosmetic, device or package;

**Natural Health Product**<sup>35</sup> : means a substance set out in Schedule 1 or a combination of substances in which all the medicinal ingredients are substances set out in Schedule 1, a homeopathic preparation or a traditional medicine, that is manufactured, sold or represented for use in

- a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state or its symptoms in humans; b) restoring or correcting organic functions in humans; or c) modifying or correcting organic functions in humans, such as modifying those functions in a manner that maintains or promotes health.

However, a natural health product does not include a substance set out in Schedule 2, any combination of substances that includes a substance set out in Schedule 2 or a homeopathic medicine or a traditional medicine that is or includes a substance set out in Schedule 2. (produit de santé naturel)

<sup>35</sup> Defined in Natural Health Products Regulations published in *Canada Gazette Part II*

1. 1. A plant or a plant material, an alga, a fungus or a non-human animal material
2. 2. An extract or isolate of a substance described in item 1, the primary molecular structure of which is identical to that which it had prior to its extraction or isolation
3. 3. Any of the following vitamins, their salts or their derivatives:
  - biotin
  - folic acid
  - niacin
  - pantothenic acid
  - riboflavin
  - Thiamine
  - vitamin A
  - vitamin B<sub>6</sub>
  - vitamin B<sub>12</sub>
  - vitamin C
  - vitamin D
  - vitamin E
3. 4. An amino acid
4. 5. An essential fatty acid
5. 6. A synthetic duplicate of a substance described in any of items 2 to 5
6. 7. A mineral
7. 8. A probiotic

## Schedule 2- Excluded Natural Health Product Substances

1. 1. A substance set out in Schedule C to the Act
2. 2. A substance set out in Schedule C or D to the Act a) a drug that is prepared from any of the following micro-organisms, namely, an alga, a bacterium or a fungus; and
  - b) any substance set out on Schedule D when it is prepared in accordance with the practices of homeopathic pharmacy
2. 3. A substance regulated under the Tobacco Act
3. 4. A substance set out in any of Schedules I to V of the *Controlled Drugs and Substances Act*

**Sell:** includes offer for sale, expose for sale, have in possession for sale and distribute, whether or not the distribution is for consideration.

## Glossary of Terms

### *Health Care Professional*

A health care professional is a graduate of an approved post-secondary program in Canada, practices according to a consensus-based code of ethics and belongs to a



self-regulating body in the provinces and territories.<sup>36</sup>

### *Relative Risk*

Risk is the combined evaluation of both safety and efficacy. Risk is evaluated by examining the safety implications at doses where a therapeutic effect is supportable. If a product only exerts its therapeutic effect when the dose becomes toxic then the risk is unacceptable. If the product is extremely safe but cannot be shown to be effective then the risk of the claim must be considered. For example when a product is very safe but cannot support a claim to treat a disease that may progress to more severe health problems (cancer for example) then the risk of such a product is unacceptable. Finally, risk is relative and needs to be considered along with the implications for morbidity and mortality under the proposed conditions for use of the product. It needs to be considered within the context of the exposure consumers have to the product. For example, if a product has an Adverse Event frequency of 1 in 10,000 exposures but successful therapy outweighs the adverse effect then a risk calculation can be based upon both the absolute risk of a product as well as a relative risk against other therapeutic choices.

### *Risk-Based Market Authorization*

A regulatory system established to ensure that all products carrying health claims on their labels are both safe and effective through pre-market authorization of allowable claims and safety requirements. Risk is the combined attributes of both safety and efficacy. Regulatory requirements increase as the risk attributable to products increases in a relative risk-based regulatory system.

36 Used by the Canadian Association of Occupational Therapists

## *APPENDIX II Schedule A, Food and Drugs Act*

Alcoholism	Gout
Alopecia (except hereditary androgenetic alopecia)	Heart disease
Anxiety state	Hernia
Appendicitis	Hypertension
Arteriosclerosis	Hypotension
Arthritis	Impetigo
	Kidney disease

Asthma  
Bladder disease  
Cancer  
Convulsions  
Depression  
Diabetes  
Disease of the prostate  
Disorder of menstrual flow  
Dysentery  
Edematous state  
Epilepsy  
Gall bladder disease  
Gangrene  
Glaucoma

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

## APPENDIX III Factors for Listing Drugs in Schedule F

Schedule F to the *Food and Drug Regulations* is a listing of chemical entities or classes of drugs, which, with exceptions, are required by regulation to be sold under prescription. The following are the factors used by the Program to determine whether this level of control over the sale of these drugs is appropriate.

Drugs will be listed in Schedule F if:

1. 1. individualized instructions and/or direct practitioner supervision, adjunctive therapy with scheduled drugs or routine laboratory monitoring is required;
2. 2. there is a narrow margin of safety between the therapeutic and toxic doses, especially in populations such as geriatrics, children and pregnant or nursing mothers;
3. 3. there are potential or known undesirable or severe side effects at normal therapeutic dosage levels;
4. 4. they are known by experimental data to induce toxicity in animals but have not been in clinical use long enough to establish the pattern or frequency of long-term toxic effects in humans;
5. 5. they are used in treatment of a serious disease easily misdiagnosed by the public;
6. 6. their use may mask other ailments;
7. 7. they have contributed to, or are likely to contribute to, the development of resistant strains of micro-organisms in humans;
8. 8. they possess a dependence or abuse potential that is likely to lead to harmful non-medical use;
9. 9. they possess a high level of risk relative to expected benefits; or
10. 10. they have a therapeutic effect based on recently elucidated pharmacological concepts, the consequences of which have not been established.

**Exceptions will be considered for drugs which:**

- a. are required to be readily available under emergency circumstances where it is not practical to obtain a prescription (such as adrenalin in insect bite kits);
- b. are rarely used without a practitioner's supervision, and where the need for free availability outweighs the need for protection under Schedule F (such as insulin and nitroglycerin); or
- c. have potential to produce dangerous interactions with other drugs or food constituents but effective labeling can minimize the risk.

## APPENDIX IV The Distinction Between Advertising and Other Activities

### POLICY from the Therapeutic Products Program

Issued: January 12, 1996 Updated:  
November 3, 2000

#### *Issue*

The Therapeutic Products Program (TPP) recognizes the importance to the pharmaceutical industry and to the general public of being able to disseminate and access non-promotional information regarding drugs for human use. The purpose of this policy is to clarify the distinction between advertising to promote the sale of a drug and activities that are not primarily intended to promote the sale of a drug (e.g., education, scientific exchange, labeling, shareholder's report, etc.).

This policy is NOT intended for use in determining whether or not the drug advertising provisions of the *Food and Drugs Act* and Regulations are observed.

#### *Scope*

This policy applies to all types of information disseminated in relation to drugs for use in humans.

#### *Background*

There are numerous provisions within the *Food and Drugs Act* and Regulations that apply to drug advertising. In order to determine the applicability of those provisions it is first necessary to determine whether or not a particular message can be considered to be advertising. For the purposes of the Act, advertising is defined as including “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”. If a message regarding a drug is not considered to promote sale or disposal, it is not subject to the advertising provisions of the *Food and Drugs Act* and Regulations.

There is a particular need to distinguish between advertising and non-promotional information in the following situations:

□.1. **Prior to market authorization:**

□.• promotion of a drug prior to market authorization is not permitted (Section 9(1) of the Act, Section C.08 002 of the Regulations) because the terms of such authorization have not been established and the proposed indication(s) for use have not been verified.

□.2. **After market authorization when information on a drug is disseminated to the general public:**

. • promotion of a prescription drug (Schedule F) to the general public is limited to name, price and quantity (Section C.01.044 of the Regulations).

. • a drug (prescription or nonprescription) may not be advertised to the general public for the treatment, preventative or cure for any Schedule A disease (Section 3 of the Act).

### *Considerations*

In determining whether a message falls within the definition of advertising, the purpose of the message is very significant. It must be determined whether the primary purpose of the message is to promote the sale of a drug or to provide information. Where the primary purpose is not clear, the following factors should be considered in determining whether the message is primarily intended to promote the sale of a drug:

*What is the context in which the message is disseminated?*

Example, when and how is the message delivered; what is the milieu or medium of dissemination? Is it a science-based message delivered to scientists/healthcare professionals by an expert, e.g., researcher at a conference with a varied agenda, or is it a product-related message delivered to a group of practicing physicians by the pharmaceutical manufacturers’ sales representative at a meeting with a limited agenda?

*Who are the primary and secondary audiences?*

Example, are the target audiences limited or unlimited in scope; are the primary and the secondary audiences the same? Where they are different, the message to the secondary audience is more likely to be advertising.

*Who delivers the message (the provider)?*

Example, the drug manufacturer/its agent or an independent third party (e.g., patient support group). Where delivered by an independent party, the message is less likely to be considered as advertising.

*Who sponsors the message and how?*

Example, the drug manufacturer/its agent or an independent third party; is the sponsorship funding targeted to a specific message, or is it added to the general operating budget for an organization, conference etc.? If the message is sponsored by an independent third party and the funding is added to the general operations budget, the message is less likely to be advertising. Where any fee is paid by the manufacturer to have the message disseminated, it is more likely to be advertising.

*What influence does a drug manufacturer have on the message content?*

Example, what are the linkages between the information, the provider and the manufacturer, the provider and the writer, etc.? Where the drug manufacturer exerts influence (e.g., preparing, editing) on the message content, it is more likely to be advertising.

*What is the content of the message?*

Example, are the facts described objectively in a balanced manner, or is emphasis placed on a particular drug or its merits; is the message balanced with respect to description of risks as well as benefits of a treatment option? Can the message withstand a test for scientific rigour? Is the information set in an appropriate context, e.g., a discussion of disease management, scientific research?

*With what frequency is the message delivered?*

Example, is it delivered once or repeatedly? Where the same message is delivered repeatedly, the message is more likely to be considered as advertising.

No one factor in itself will determine whether or not a particular message is advertising. Each message must be evaluated on its own merit and other factors may apply.

Examples of messages delivered in different contexts are discussed in Appendix I.<sup>37</sup> The list of examples is intended as a guide only and is not all inclusive. The same factors for consideration will be applied to other types of messages not listed here.

This clarification should assist in distinguishing between advertising and non-promotional information. It is only after having determined that the primary purpose of a message is advertising that an assessment can be made regarding compliance with the regulations pertaining to drug advertising.

## *Implementation*

Since this policy serves to clarify and expand upon the current interpretation of the definition of advertising within the *Food and Drugs Act*, it is effective immediately upon publication, and replaces the Drugs Directorate Policy, Distinctions between Advertising and Educational Activity, dated October 7, 1991.

37 For full document including Appendices, see

[http://www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpt/advfactv\\_e.html](http://www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpt/advfactv_e.html)

# APPENDIX V Regulatory Overview – Health Claims Permitted on Foods Advertised and Sold in Canada

## General Requirements

1. 1. Section B.01.311 of the *Food & Drug Regulations* states that “a claim may be made to the effect that the substance in respect of which the claim is made is **generally recognized as an aid in maintaining the functions of the body necessary to the maintenance of good health and normal growth and development.**”

2. 2. The type of claims recognized by B.01.311 are often referred to as “textbook claims” and thus have been widely recognized by the scientific community for a long time.

3. 3. Section D.01.006 (vitamins in foods regulations) states that “*No person shall, on the label or in any advertisement for a food, make any claim concerning the action or effects of a vitamin contained in the food, except to the effect that the vitamin:*

*.(a) is a factor in the maintenance of good health; and*

*.(b) is generally recognized as an aid in maintaining the functions of the body necessary to the maintenance of good health and normal growth and development*

4. Section D.02.004 (minerals in foods regulations) states that “*No person shall, on the label or in any advertisement for a food, make any claim concerning the action or effects of a mineral nutrient contained in the food, except to the effect that the nutrient*

*.(a) is a factor in the maintenance of good health; and*

*.(b) is generally recognized as an aid in maintaining the functions of the body necessary to the maintenance of good health and normal growth and development.*

## CFIA Guide to Food Labeling and Advertising

1. 5. The CFIA has interpreted Sections B.01.311, D.01.006 and D.02.004 in Section 7.5.1 of the *Guide to Food labeling and Advertising*. Section 7.5.1 is entitled: ***Biological Role of Nutrients***.

2. 6. The CFIA *Guide to Food Labeling and Advertising* represents the interpretation of the federal government (CFIA with advice from Health Canada and other departments) about the intent and interpretation of labeling and advertising regulations. **The Guide is not a legal document but simply a tool to assist with compliance and consumer protection. As the *Food and Drugs Act* is considered to be part of the Criminal Law of Canada, only a Court of Law can make legal interpretations about the scope and applicability of sections of the Act itself and the subservient regulations promulgated under the authority of the Act.**

3. 7. **Section 7.5.1 of the Guide** states that the *Food and Drugs Act* and *Regulations (B.01.311, D.01.006 and D.02.004)* permits claims for the action of the following nutrients:

- i. Protein
- ii. Fat
- iii. Carbohydrate
- .iv. Sugar (all monosaccharide and disaccharides)
- .v. Sorbitol
- vi. Mannitol
- vii. Xylitol
- viii. Starch
- .ix. Dietary fibre
- .x. Amino acids
- xi. Linoleic acid
- xii. *cis*-methylene interrupted polyunsaturated fatty acids
- xiii. *cis*-monounsaturated fatty acids
- xiv. saturated fatty acids
- xv. vitamins and mineral nutrients listed in Tables 1 and 2 of Part D of the Regulations

1. 8. The claim **may not** refer directly or indirectly to the treatment, mitigation or prevention of any disease, disorder or abnormal physical state, or symptoms of same, **nor may it** refer directly or indirectly to correcting, restoring or modifying organic functions. This brings the product within the ambit of a “drug”.

2. 9. **The claim may not refer directly or indirectly to the treatment, prevention or cure of diseases listed in Schedule A of the *Food and Drugs Act*, Subsection 3(1).**

Examples of Acceptable Claims

10. “Calcium aids in the growth and maintenance of bones and teeth” “ Protein is needed for the maintenance and repair of body tissues”.

### Examples of Unacceptable Claims

11. “Calcium fights bone diseases such as osteoporosis”  
 “Protein builds muscles and makes you stronger”

### Compositional Requirements

12. A minimum level of the nutrient must be present in the food. In the case of protein, a reasonable daily intake must have a protein rating of at least 20; in the case of vitamin and mineral nutrients, a serving of stated size must contain at least 5 percent of a “recommended daily intake” of the nutrient.

### Other Interpretations Respecting Acceptable and Unacceptable Claims

13. The claims for the action or biological role on nutrients should not imply that consumption of the food, by itself, will have the effect attributed to the nutrient: An **acceptable** claim would be “**Milk is an excellent source of calcium which helps build strong bones and teeth.** n **unacceptable** claim would be “**Milk helps build strong bones and teeth**” 14. Table of Acceptable Specific Claims Summarized in Section 7.5.2 of the Guide

Protein	-helps build and repair body tissues -helps build antibodies
Fat	-supplies energy -aids in the absorption of fat-soluble vitamins
Carbohydrate	-supplies energy -assists in the utilization of fats
Vitamin A	-aids in normal bone and tooth development -aids in the development and maintenance of night vision -aids in maintaining the health of the skin and membranes
Vitamin D	-factor in the formation and maintenance of bones and teeth -enhances calcium and phosphorus absorption and utilization
Vitamin E	Protects the fat in body tissues from oxidation
Vitamin C	Factor in the development and maintenance of bones, cartilage, teeth and gums
Thiamine (Vitamin B1)	-releases energy from carbohydrate -aids in normal growth
Riboflavin (Vitamin	-factor in energy metabolism and tissue formation



B2)	
Niacin	-aids in normal growth and development -factor in energy metabolism and tissue formation
Vitamin B6	-factor in energy metabolism and tissue formation
Folacin	-aids in red blood cell formation
Vitamin B12	-aids in red blood cell formation
Pantothenic Acid	-factor in energy metabolism and tissue formation
Calcium	-aids in the formation and maintenance of bones and teeth
Phosphorus	-factor in formation and maintenance of bones and teeth
Magnesium	-factor in energy metabolism, tissue formation and bone development
Iron	-factor in red blood cell formation
Zinc	-factor in energy metabolism and tissue formation
iodine	-factor in the normal function of the thyroid gland

### Diet and Disease Information Which Does Not Offend Section 3 of the *Food and Drugs Act*

1. 15. Section 7.11.2 of the *Guide to Food Labeling and Advertising* deals with statements that do not offend Section 3 of the *Food and Drugs Act*.

2. 16. A statement such as “**a diet low in saturated fat may help reduce the risk of heart disease**” is permissible only if **no** linkage is made to a specific food product.

□.17. Section 7.11.2 of the *Guide* details the following fact situations that are **not considered to offend subsections 3(1) and 3(2)** of the Act:

- Messages which are non-product specific, describing the role of diet in disease prevention with corporate announcements (e.g. public service announcements);
- Books and educational material which describe the role of diet in disease prevention with corporate sponsorship or corporate brand sponsorship providing that such is not deemed to be an advertisement for the food product;
- Dietary guidelines/recommendations on food labels and in advertising which are endorsed by a non-governmental health agency but which do not mention disease prevention or cure.

### Claims Respecting Treatment of Other Diseases

18. Section 7.11.3 of the *Guide* states that “Although there is no specific prohibition against the advertising of a food for the prevention or cure of diseases other than those listed in Schedule A, such claims bring the food within the definition of a drug under the *Food and Drugs Act*, Section 2, which defines a drug as “*any substance or mixture of substances manufactured, sold or represented for use in:*

□. (a) *the diagnosis, treatment, mitigation or prevention of a disease, disorder, abnormal*

*physical state, or the symptoms thereof, in man or animal*

□.(b) *restoring, correcting or modifying organic functions in man or animal*”

## Generic Health Claims – Promulgated December 12, 2002

19. The promulgation of a Schedule of Amendments dealing with Mandatory Nutrition Labeling, Nutrient Content Claims and Health Claims on December 12, 2002 ushered in a new era of generic health claims patterned after similar claims that have been legal in the U.S.A. since 1994.

1. 20. While some 13 generic health claims are permitted on foods in the U.S.A., at the present time only 5 such health claims are permitted in Canada.

2. **21. Section B.01.601** states the following:

□.(1) A food with a label or advertisement that carries a statement or claims set out in column 1 of the table following section B.01.603 is exempt from the provisions of the Act and its Regulations with respect to drugs, and from subsections 3(1) and (2) of the Act, if

□.(a) the food meets the applicable conditions set out in column 2;

□.(b) the label of or the advertisement for the food meets the applicable conditions set out in column 3, and

□.(c) the food is not intended solely for children under two years of age or a food represented for use in a very low energy diet.

□.(2) Subsection (1) does not apply to a food that comes within the definition of a “drug” as defined in Section 2 of the Act for reason other than the fact that its label or advertisement carries a statement or claim referred to in that subsection.

□.(3) Subsection (1) applies even if the word “graisse” in the French version of the statement or claim is replaced by the word “lipides”.

22. Clearly, the claims found in the table to Section B.01.601 have been legally validated through the use of the “exemption clause” found in Section 30(1)(j) of the *Food and Drugs Act*. Section 30 of the Act defines the type of regulations that may be promulgated pursuant to the Act and includes the “exemption clause” which permits

***exempting any food, drug, cosmetic or device from all or any of the provisions of this Act and prescribing the conditions of the exemption.***

### Examples of the Type of Generic Health Claims that are Permitted

1. 23. Claims dealing with the dietary relationship between potassium and sodium and high blood pressure, stroke and heart disease: “A healthy diet containing food high in potassium and low in sodium may reduce the risk of high blood pressure, a risk factor for stroke and heart disease. (Naming the food) is sodium-free”.

2. 24. Claims dealing with diet, calcium, vitamin D, physical activity and osteoporosis: “A healthy diet with adequate calcium and vitamin D, and regular physical activity, help to achieve strong bones and may reduce the risk of osteoporosis. (Naming the food) is a good source of calcium”

3. 25. Claims dealing with diet, saturated fats and trans fats and heart disease: “A healthy diet low in saturated and trans fats may reduce the risk of heart disease. (Naming the food) is free of saturated and trans fats”
4. 26. Claims dealing with a diet rich in fruits and vegetables and some types of cancer: “A healthy diet rich in a variety of vegetables and fruit may help reduce the risk of some types of cancer”.
5. 27. Claims dealing with foods that do not promote dental caries: “Won’t cause cavities”, “Does not promote tooth decay”, “Does not promote dental caries”, “Non-cariogenic”.

### Using Generic Health Claims on Food Labels and in Advertising

28. The scheme put in place on December 12, 2002 permits a food manufacturer to use one of the claims prescribed in the regulations on condition that the food meets with the conditions prescribed for that particular claim. This type of scheme does not require pre-market control or registration as the onus for producing a compliant product rests with the food manufacturer. With this type of scheme, all compliance and enforcement by government is “post-market”.

### An Example of a Claim that Can not be Made on Food Products

1. 29. The tea industry and manufacturers that use tea as an ingredient have long desired to make a statement respecting the antioxidant properties of various types of tea. In the U.S.A., such statements have been accepted or at least tolerated by the FDA. In Canada, the CFIA and Health Canada have concluded that such claims cannot be scientifically substantiated and that the proposed statement about “neutralizing free radicals” is an indirect reference to a Schedule A disease – cancer.
2. 30. As noted earlier in this overview (table in para 14), a claim respecting the antioxidant properties of vitamin E is the sole such claim that has been interpreted as being generally accepted by the scientific community.
3. 31. Claims for specific constituents (such as the antioxidants in tea) found in conventional foods and other substances found in “functional foods” and “nutraceuticals” raises a number of questions.
4. 32. In most cases, the claims involve either a direct or indirect reference to a disease listed in Schedule A. Resolution of the problems created by Section 3 and Schedule A represent the first part of the solution to the issue of dealing with “new” food constituents that have value in terms of reducing disease risk.
5. 33. The second part of the problem relates to the fact that there is currently no defined process for demonstrating that constituents that do not fall into the category of “textbook claims” have a high degree of scientific acceptance and credibility. Canadian regulators seem very reluctant to accept the type of scientific evidence that is acceptable to support label and advertising claims (e.g. antioxidants in tea) used in the United States.

## APPENDIX VI Canadian Code of Advertising Standards Provisions

The Code is widely supported by all participating organizations, and is designed to help set and maintain standards of honesty, truth, accuracy, fairness and propriety in advertising.

No advertising that contravenes this Code shall be prepared or knowingly exhibited by the participating organizations.

The provisions of the Code should be adhered to both in letter and in spirit. Advertisers and their representatives must substantiate their advertised claims promptly when requested to do so by a Council.

## 1. Accuracy and Clarity

□.(a) Advertisements must not contain inaccurate or deceptive claims, statements, illustrations or representations, either direct or implied, with regard to a product or service. In assessing the truthfulness and accuracy of a message, the concern is not with the intent of the sender or precise legality of the presentation. Rather, the focus is on the message as received or perceived, i.e. the general impression conveyed by the advertisement.

□.(b) Advertisements must not omit relevant information in a manner that, in the result, is deceptive.

□.(c) All pertinent details of an advertised offer must be clearly and understandably stated.

□.(d) Disclaimers and asterisked or footnoted information must not contradict more prominent aspects of the message and should be located and presented in such a manner as to be clearly visible and/or audible.

□.(e) Both in principle and practice, all advertising claims and representations must be supportable. If the support on which an advertised claim or representation depends is test or survey data, such data must be reasonably competent and reliable, reflecting accepted principles of research design and execution that characterize the current state of the art.

At the same time, however, such research should be economically and technically feasible, with due recognition of the various costs of doing business.

(f) The entity that is the advertiser in an advocacy advertisement must be clearly identified as the advertiser in either or both the audio or video portion of the advocacy advertisement.

## 2. Disguised Advertising Techniques

No advertisement shall be presented in a format or style which conceals its commercial intent.

## APPENDIX VII Reaching Canadians – Some

# Statistics on Canada's Media Industries

## The Canadian Broadcasting Industry

- . • 484 English conventional television and specialty and pay services
- . • 109 French television services
- . • 27 third-language television services
- . • 597 English radio stations
- . • 199 French radio stations
- . • 18 third-language radio stations
- . • On average Canadians watch 25.1 hours of television a week
- . • Television reaches 85% of adults over 18.
- . • Radio reaches 76% of adults over 18.
- . • Internet reaches 34% of adults over 18.

## Canadian Newspaper Industry

- . • 102 dailies in Canada
- . • Newspapers reach 66% of adults over 18
- . • 13 million Canadians have read a newspaper by the end of the week.

**“Consumers read the newspapers as much for the advertising as the editorial content.” Source: Readership Institute, 2002 U.S.**

U.S. data shows Health ranks in the top third of editorial content up therewith war and politics.

## The Canadian Magazine Industry

- . • There are 1,000 Canadian consumer magazines available in Canada plus an additional 1,000 Canadian trade, farm, religious and scholarly magazines. It is estimated that an additional 2,500 foreign publications, primarily U.S.-based, are available in Canada.
- . • Magazines reach 42% of adults over 18
- . • 35% of Canadians read a magazine yesterday
- . • 89% of Canadians read a magazine each month
- . • 99% of Canadians read a magazine annually
- . • Approximately 518 million Canadian consumer magazine copies are distributed annually (roughly 43 million monthly)

## Canadian the Advertising Industry

- . • Total world advertising expenditure in measured media projected for 2001 is \$481.1 billion, an increase of 3.7% over 2000
- . • Total world advertising expenditure in non-measured media is estimated at \$721.5 billion, for a total global disposable expenditure of U.S.\$1,202 trillion
- . • Estimated aggregate expenditure of the Canadian advertising industry totaled \$16.79 billion in 2000
- . • Approximately 79% of total advertising expenditures in Canada remain in

the Canadian economy.

## APPENDIX VIII International Comparison

The two major trading partners of Canada with similar restrictions are the European Union and Australia<sup>38</sup>.

### 4.3.1 The EU Situation

In Europe the Commission of European Communities have a schedule-A like regulation found under article 88 of DIRECTIVE 2001/83/EC. This states:

- .1. *Member States shall prohibit the advertising to the general public of medicinal products which:*
- . • *Are available on medical prescription only, in accordance with Title VI,*
  - . • *Contain psychotropic or narcotic substances, such as the United Nations Conventions of 1961 and 1971,*
  - . • *May not be advertised to the general public in accordance with the second subparagraph of paragraph 2.*
2. 2. *Medicinal products may be advertised to the general public which, by virtue of their composition and purpose, are intended and designed for use without the intervention of a medical practitioner for diagnostic purposes or for the prescription or monitoring of treatment, with the advice of the pharmacist, if necessary.*

*Member States shall prohibit the mentioning in advertising to the general public of therapeutic indications such as:*

- . • *Tuberculosis,*
- . • *Sexually transmitted diseases,*

38 Sections on EU and Australia have been provided by Nonprescription Drug Manufacturers of Canada: Memo from David Skinner to Schedule A Advisory Committee entitled: Schedule A legislation elsewhere, May 16, 2003

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- . • *Other serious infectious diseases,*
- . • *Cancer and other tumoral diseases,*
- . • *Chronic insomnia,*
- . • *Diabetes and other metabolic illnesses.*

It should be noted however, that the European Commission has proposed to delete the list of diseases. The European Parliament and Council of Ministers are in agreement with such a change but have not yet decided upon a time frame for change.

### 4.3.2 The Australian Situation

The essence of the Australian regulation is to have a very limited list of prohibited representations and then for a larger list of diseases where claims are allowed only when approved by government review. This is to ensure that substances that are not required to register as therapeutic goods cannot make such claims without going through government approval.

#### *Part 1 - Prohibited Representations*

***A prohibited representation is defined as:***

*Any representation regarding abortifacient action*

*(ii) Any representation regarding the treatment, cure or prevention of the following diseases:*

- . *• Neoplastic*
- . *• Sexually Transmitted Diseases (STD)*
- . *• HIV AIDS and/or HCV*
- . *• Mental illness*

***Except for the following representations that are to become restricted representations:***

*(i) Prevention of skin cancer through the use of sunscreens*

*(ii) Devices used in contraception or in the prevention of transmission of disease between persons*

#### *Part 2 - 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.*

Table 1. 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
- Hematological 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

There are no immediate plans to change this regulation other than the noted exceptions for sunscreens and condoms.

Both European and the Australian authorities have made their regulations more recently than Canada and have moved significantly to the approach that allows claims for almost any condition provided that the government approves the claim based on evidence provided.

#### 4.3.3 United States<sup>39</sup>

As noted by Curran<sup>40</sup>, 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.<sup>41</sup>

#### 4.3.4 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

39 Sections on United States and the World Health Organization are quoted from *Summary of Issues for the Working Group on sections 3 and Schedule A*, Health Canada, May 7, 2003

40 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*.

41 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>

conditions that can be treated only by qualified health practitioners, for which certain countries have established lists.

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.**<sup>42</sup> (emphasis added)

## APPENDIX IX

# International Overview of Health Claims on Foods

### Australia/New Zealand

Current legislation in Australia and New Zealand prohibits claims of a therapeutic or preventative nature, use of the word “health” on labels or in advertisements and the provision of medical advice in association with foods. Food regulation and regulatory policy in Australia and New Zealand is handled jointly by an agency called the Australia-New Zealand Food Authority (ANZFA).

Proposal 153 – “A Review of Health and Related Claims” was developed by ANZFA and was given limited distribution in May 2002. No clear consensus has emerged about permitting health claims on foods and the issue is still under active review. However, the pilot program dealing with the relationship between folic acid and neural tube defects is ongoing and permission to make the folate/NTD health claim has been extended until February 13, 2004.

### European Union

EU Framework Directive 79/112 prohibits the use of medical and health claims on food labels and in advertising. This directive was implemented in all member states in 1982. However, the tolerance for such claims appears to vary considerably among the member states of the E.U.

A draft directive was released in July 1993 with the hope that community rules could be established to provide greater clarity to the issue of health and nutrition claims. This draft was ultimately withdrawn as a result of lack of consensus in terms of the need and appropriateness of proceeding with a specific proposal in light of the requirements found in the Framework Directive 79/112.

The issue of claims has resurfaced again with the announcement on July 16, 2003 that the European Commission has agreed upon new rules to outlaw misleading claims on food labels, forcing industry to stick to slogans that can be backed up by science. Vague claims about foods aiding weight loss or helping the body resist stress would be removed from packaging, as would eye-catching labels that glossed over a product’s fat content.

Food manufacturers will also be able to use label claims stating that a food reduces the risk of disease for the first time, once the claim is backed up by science.

EU governments and the European Parliament have to approve the draft before

it can apply across the EU, expected by 2005.

## Japan

The concept of “Foods for Specified Health Use” (FOSHU) was introduced in Japan in 1991 for the purpose of providing the consumer with food products with strongly suggestive health benefits based on sound, scientific research data. The label of the food is permitted to include a label claim that a person who uses the product for “specified health use” may expect to obtain the health benefit through consumption of the product.

The FOSHU system is complex. A food and its added ingredients must meet a number of criteria. For example, functional ingredients must have proven medical and nutritional benefits. The serving size and quantity of ingredient intake must be agreed upon by medical and nutritional scientists and analytical tests must be approved. The food must typically be included in the diet, and cannot be in the shape of a tablet or capsule or be used as a medicine.

After a food has been approved, it may bear an agreed-upon statement indicating its specific health benefit and a Ministry of Health and Welfare seal of approval.

## United States of America

Health claims for foods and dietary supplements are both subject to the *Nutrition Labeling and Education Act (NLEA)* which requires pre-market approval or authorization by the FDA. Under the NLEA, the FDA must determine, based on “the totality of publicly available evidence” that a claim is supported by “significant scientific agreement, among experts qualified by scientific training and experience”.

Health claims in the following specific areas can be made on foods sold in the U.S.A. providing that the composition of the food complies with specific regulatory requirements:

- . • Calcium and osteoporosis
- . • Dietary Lipids and Cancer
- . • Dietary Saturated Fat and Cholesterol and Risk of Coronary Heart Disease
- . • Dietary Sugar Alcohol and Dental Caries
- . • Fiber-containing Grain Products, Fruits and Vegetables and Cancer
- . • Folic Acid and Neural Tube Defects
- . • Fruits and Vegetables and Cancer
- . • Fruits, Vegetables and Grain Products that contain Fiber, particularly Soluble fiber, and Risk of Coronary Heart Disease
- . • Sodium and Hypertension
- . • Soluble Fiber from Certain Foods and Risk of Coronary Heart Disease
- . • Soy Protein and Risk of Coronary Heart Disease

- Stanol/Sterols and Risk of Coronary Heart Disease

On July 10, 2003, the FDA announced that it will accept applications to place “qualified” health claims on food labels beginning September 1, 2003. Among the first to be considered: eating several servings a week of salmon and certain other fish rich in omega-3 fatty acids is thought to, but not proven to, reduce the risk of heart disease.

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Until the July 10 proposal, the FDA has enforced a very strict standard about what health claims could be made on a food label. Under the new program, the FDA will give a grade to applications for new health claims. “A” for scientifically proven claims; “B” where the science is good but not conclusive; “C” when there is limited science to support the claim; and “D” when there is hardly any science to support the claim.

Claims such as “calcium prevents bone-weakening osteoporosis” would constitute an A-rated claim. This type of claim is already permitted and would not change.

Claims rated a “B”, “C” or “D” would be considered qualified, and for the first time could be put on a food label next to a short disclaimer that describes the level of proof. Whether the letter grade itself will also go on packages is still under consideration.

This proposal has resulted in both praise and criticism. Consumer advocacy groups feel that the proposal will result in “wishy-washy” health advice and will confuse the consumer. There is also concern that when consumers see a claim on a product and later learn it was a false claim, they may decide that none of the label claims on food products have any value.

The food industry has taken the view that low-rated claims make sense in the wake of recent court rulings that allow more loosely regulated dietary supplements to make more far-reaching claims about health effects.

## **APPENDIX X**

### **Schedule A Medium-Term Recommendation Case Studies**

**Psyllium Studies**

## *Schedule A Disease State: Arteriosclerosis*

The cholesterol-lowering effect of psyllium in both men and women has been demonstrated through many robust clinical trials. This in turn should enable psyllium-containing products to make risk-reduction claims with respect to arteriosclerosis or conditions/symptoms deemed synonymous with the disease.

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## St. John's Wort Studies

### *Schedule A Disease State: Depression*

Hypericum has been demonstrated to be effective in treating the symptoms of mild to moderate depression. The evidence below not only

outlines the effectiveness of hypericum, it also compares its relative effectiveness to various other treatments used by health care professionals to treat more serious depression.

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## Sunscreen Studies

### *Schedule A Disease State: Cancer*

A wide body of evidence exists to support the use of sunscreens as a risk-reduction measure for various types of carcinomas of the skin. The consumer is entitled to this information through product claims to make an informed decision regarding reducing the risk of acquiring this potentially fatal disease.

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## Tea Studies

### *Schedule A Disease State: Cancer*

There is increasing evidence that specific substances found in certain foods can enhance general healthy eating recommendations, e.g. phenolic compounds found in plants. Tea is a rich in specific phenolic compounds including flavonoids.

Flavonoids are powerful antioxidants found in a number of foods, including tea, and have been identified as dietary components associated with risk reduction of certain diseases, including cancer. Tea has been shown to inhibit the tumor initiation, promotion and progression stages of

cancer. It has been suggested that possible mechanisms for the action of flavonoids could include: antioxidant activity; ability to inhibit nitrosamine reactions; modulation of carcinogen-metabolizing enzymes; trapping of ultimate carcinogens; ability to inhibit cell proliferation; modulation of gut microflora and antimicrobial action.

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## Glucosamine Therapy for Treating Osteoarthritis

### *Schedule A Disease State: Arthritis*

Below, the systematic meta-analysis of studies which include randomized controlled trials (RCTs) linking glucosamine as an effective treatment for osteoarthritis, is one of the highest forms of scientific support available to prove the efficacy of a substance in treating a disease or the symptoms thereof.

### **Abstract**

Towheed TE, Anastassiades TP, Shea B, Houpt J, Welch V, Hochberg MC. A substantive amendment to this systematic review was last made on 08 December 1999. Cochrane reviews are regularly checked and updated if necessary.

**Background:** Osteoarthritis (OA) is the most common form of arthritis, and it is often associated with significant disability and an impaired quality of life.

**Objectives:** To review all randomized controlled trials (RCTs) evaluating the effectiveness and toxicity of glucosamine in osteoarthritis (OA).

**Search strategy:** We searched MEDLINE, Embase, and Current Contents up to November 1999, and the Cochrane Controlled Trials Register. We also wrote letters to content experts, and hand searched reference lists of identified RCTs and pertinent review articles.

**Selection criteria:** Relevant studies met the following criteria: 1) RCTs evaluating the effectiveness and safety of glucosamine in OA, 2) Both placebo based and comparative studies were eligible, 3) Both single blinded and double-blinded studies were eligible.

**Data collection and analysis:** Data abstraction was performed independently by two investigators and the results were compared for degree of agreement. Gotzsche's method and a validated tool (Jadad 1995) were used to score the quality of the RCTs. Continuous outcome measures were pooled using standardized mean differences. Dichotomous outcome measures were pooled using Peto Odds Ratios.

**Main results:** Collectively, the 16 identified RCTs provided evidence that glucosamine is both effective and safe in OA. In the 13 RCTs in which glucosamine was compared

to placebo, glucosamine was found to be superior in all RCTs, except one. In the four RCTs in which glucosamine was compared to and NSAID, glucosamine was superior in two, and equivalent in two.

**Reviewers' conclusions:** Further research is necessary to confirm the long term effectiveness and toxicity of glucosamine therapy in OA. Most of the trials reviewed only evaluated the Rotta preparation of glucosamine sulfate. It is not known whether different glucosamine preparations prepared by different manufacturers are equally effective in the therapy of OA.

**Citation:** Towheed TE, Anastassiades TP, Shea B, Houpt J, Welch V, Hochberg MC. Glucosamine therapy for treating osteoarthritis (Cochrane review). In: *The Cochrane Library*, Issue 3 2002. Oxford: Update Software.

## Acetylsalicylic Acid (ASA) Studies

### *Schedule A Disease State: Heart Disease*

The overwhelming body of scientific evidence below supports the use of ASA to reduce the risk of various forms of heart disease. Risk reduction claims for conditions or symptoms synonymous with heart disease are necessary to provide consumers with credible information to make an informed decision regarding their long-term health.

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## APPENDIX XI

### External Working Group Process: Meetings and Teleconferences

The mandate of the Schedule A External Working Group set out a period of between six and ten months within which the group would discuss, debate, and develop its report on Schedule A. Between April and December 2003, Working Group members developed their recommendations through face-to-face meeting, teleconferences, sub-working groups and telephone and e-mail exchanges.

The Working Group met formally in Ottawa six times and participated in three teleconferences. In addition, five sub-working groups met several times to further



develop the recommendations of the Working Group.

Throughout this process, the Working Group members reviewed various analytical and research pieces, analyzed complex issues, engaged in extensive debate, and ensured that diverse views were reflected in their work.

## Meetings and Teleconferences

April 28, 2003 – *First Working Group Meeting*

- Working Group members were introduced to the issues surrounding Schedule A, brainstormed on an approach, set initial priorities and next steps.

May 26 – 27, 2003 – *Second Working Group Meeting*

- The Working Group reviewed its mandate and focused upon developing its framework.

June 25 – 26, 2003 – *Third Working Group Meeting*

- The Working Group reviewed the first draft of the report outline and reviewed the project framework.

August 6, 2003 – *Teleconference*

- Discussion of short term and medium term options and began review of the long term option.

August 21, 2003 – *Teleconference*

- Continued discussion of the medium term options.

August 27-28, 2003 – *Forth Working Group Meeting*

- In addition to reviewing the second draft of the report the Working Group developed and analyzed its options based upon its guiding principles.

September 15, 2003 – *Teleconference*

- Discussion of the medium term option as well as review of Schedule A diseases

September 22-23, 2003 – *Fifth Working Group Meeting*

- The Working Group finalized its review of Schedule A diseases and developed criteria to determine when a disease should be listed or de-listed. Furthermore, the group clarified the linkages between the Working Group's long term recommendations and the Legislative Renewal process.

October 10 to 31, 2003, *E-mail correspondence – Sub Working Group Three*

- Review of medium term recommendation via e-mail correspondence

October 16, 2003 – *Teleconference – Sub Working Group Two*

- Review of long term recommendations

October 22, 2003 – *Teleconference – Sub Working Group Two*

- Further development of long term recommendations
- Review of report introduction and context

- Review of short term recommendations
- Review of last revised draft

October 23, 2003 – *Teleconference – Sub Working Group One*

October 24, 2003 – *Teleconference -Sub Working Group Four*

November 14, 2003 – *Teleconference -Sub Working Group Five*

December 2, 2003 – Chairs discuss final meeting

December 8-9, 2003 – *Sixth and Final Working Group Meeting*

- Finalization of Report