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

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Executive Summary
Sections 5, 9 and 20 of the *Food and Drugs Act* prevent a variety of deceptions regarding foods, drugs and medical devices. For consumer products, the deception provisions reside in the *Competition Act*.

All interested parties agree that a deception provision is necessary in the new health protection legislation for all health products and consumer products. Although the current provision has served us well over the years and is well written when compared to what is found in other jurisdictions, it could be improved on a number of fronts: it should leave little room for subjectivity by describing as much as possible violations that are clear and objective; it should apply to all products regardless of their classification; it should be a violation to publish deceptive material; there should be a requirement to demonstrate the truthfulness of a health claim; and the onus should be on the manufacturer to demonstrate the validity of the claim.

1. ISSUE
To determine what provisions should be included in the proposed Canada's Health Protection Act to prevent deception of the public.

2. BACKGROUND AND ISSUE ANALYSIS

2.1 Background
Sections 5, 9 and 20 of the *Food and Drugs Act* prohibit a variety of deceptions involving foods, drugs and medical devices:

> 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.*
>
> *(2) A food that is not labelled or packaged as required by, or is labelled or packaged contrary to, the regulations shall be deemed to be labelled or packaged contrary to subsection (1).*
>
> *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.*
>
> *(2) A drug that is not labelled or packaged as required by, or is labelled or packaged contrary to, the regulations shall be deemed to be labelled or packaged contrary to subsection (1).*
>
> *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 design, construction, performance, intended use, quantity, character, value, composition, merit or safety.*

> *(2) A device that is not labelled or packaged as required by, or is labelled or packaged contrary to, the regulations shall be deemed to be labelled or packaged contrary to subsection (1).*[1]

The *Hazardous Products Act* does not deal with deception for consumer products, but relies on Sections 52 and 74 of the *Competition Act*:

> *52. (1) No person shall, for the purpose of promoting, directly or indirectly, the supply or use of a product or for the purpose of promoting, directly or indirectly, any business interest, by any means whatever, knowingly or recklessly make a representation to the public that is false or misleading in a material respect.*
>
> *74.01(1) A person engages in reviewable conduct who, for the purpose of promoting, directly or indirectly, the supply or use of a product or for the purpose of promoting, directly or indirectly, any business interest, by any means whatever,*
>
> *1. makes a representation to the public that is false or misleading in a material respect;*
>
> *2. makes a representation to the public in the form of a statement, warranty or guarantee of the performance, efficacy or length of life of a product that is not based on an adequate and proper test thereof, the proof of which lies on the person making the representation; or,...*

2.1.1 Origin of Sections 5, 9, and 20 of the *Food and Drugs Act*

Prior to the 1953 *Food and Drugs Act*, the provisions dealing with misbranding and adulteration included both food and drugs (see below Sections 25, 22, 7). Drugs were then considered to include both devices and cosmetics, so the evolution of the deception clause for foods, drugs and devices is common.

Several Sections of earlier legislation were combined to create Sections 5, 9 and 20 of the 1953 *Food and Drugs Act*. In order to better understand the current provisions, it is helpful to examine their origins.

A provision containing some of the elements found in Section 9 first appeared in the *Adulteration Act* of 1885;

> *25. Every person who knowingly attaches to any article of food, or any drug, any label which falsely describes the article sold, or offered or exposed for sale, shall incur a penalty not exceeding one hundred dollars and not less than twenty dollars, with costs.*[2]

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[1] Departmental Consolidation of the *Food And Drugs Act* and of the *Food And Drug Regulations* with amendments to December 15, 1995.

[2] 48-49 Victoria., c.67, s.25.

This was renumbered as Section 37 in 1906[3] and, with some modifications, became Section 22 of the *Food and Drugs Act* of 1920. A significant addition to the Act in 1920 was the offense of neglecting or refusing to label a food or drug in accordance with the requirements of the Act. This provision, which reads as follows, is similar to subsection 9(2) of the current legislation:

> *22. Every person who attaches to any article or package of food or drug sold or offered or exposed for sale any label or mark containing any untrue or misleading name, device or statement, or who neglects or refuses to label or mark any article or package of food or drug in accordance with the requirements of this Act, shall for a first offence be liable, upon summary conviction, to a fine not exceeding two hundred dollars and costs and not less than fifty dollars and costs, or to imprisonment for any term not exceeding three months, or to both fine and imprisonment, and for each subsequent offense to a fine not exceeding three hundred dollars and costs and not less than fifty dollars and costs or to imprisonment for any term not exceeding six months, or to both fine and imprisonment.*[4]

The fraudulent representation of food was also dealt with by a statutory definition of misbranding which was added to the Act in 1920[5]. The definition was expanded to include drugs in 1927.

> *7. Food or drug shall be deemed to be misbranded within the meaning of this Act*
> *(a) if it is an imitation of, or substitute for, or resembles in a manner likely to deceive, another article of food or drug under the name of which it is sold or offered or exposed for sale and is not plainly and conspicuously labelled so as to indicate its true character;*
> *(b) if it is stated to be a product of a place or a country of which it is not truly a product;*
> *©) if it is sold or offered for sale by a name which belongs to another article*
> *(d) if it is so coloured or coated, powdered or polished that damage is concealed, or if it is made to appear better or of greater value than it really is;*
> *(e) if false or exaggerated claims are made for it upon the label or otherwise;*
> *(f) if in package form, sealed by or put up by the manufacturer or producer, and bearing his name and address, the contents of each package are not conspicuously and correctly stated within limits of variability to be fixed by regulations as in this Act provided, in terms of weight, measure or number, upon the outside of the package: Provided that this paragraph shall not apply to packages the weight of which including the package and contents is under two ounces; and that nothing in this section shall be taken to require the statement of weight, measure or number upon containers or packages of standard size as provided by orders of the Governor in Council under the Meat and Canned Foods Act;*
> *(g) if it is not labelled in accordance with the requirements of this Act;*
> *(h) if the package containing it, or the label on the package, bears any statement, design or device regarding the ingredients or the substances contained therein, which statement, design, or device is false or misleading in any particular; or if the package is deceptive with respect to design; construction or fill; or*
> *(I) if the package containing it, or the label on the package, bears the name of an individual*

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[3] R.S.C. (1906), c. 133.

[4] *Food and Drugs Act*, S.C. 1920, (10-11 George V), c. 27.

[5] Supra, note 4

or of a company, claimed to be the manufacturer or producer of the article, which individual or company is fictitious or non-existent.[6]

The statutory definition of misbranding, introduced in 1920, covers many of the same offenses as the false label or neglect to label provision. It is interesting to note that under the *Food and Drugs Act* of 1927 a false or untrue label on a drug product could be prosecuted under subsection 7.(e), misbranding, or Section 32, false label or neglect to label (a similar situation had existed for Foods since 1920) .

The Sections of the Act pertaining to misbranding and false label or neglect to label were included, essentially unchanged, as Sections 8 and 35, respectively, in the revised statutes of 1952.

When the *Food and Drugs Act* was extensively revised in 1953, it was recognized that because devices and cosmetics are inherently different from drugs, it would be more appropriate when making provisions for their manufacture and sale to treat them as different products rather than to deal with them by artificially including them in the definition of a drug. This is the reason why, in 1953, foods, drugs and devices each received their own Section on deception[7]. There was no corresponding provision for cosmetics because it was felt that cosmetic advertising is traditionally of a more exaggerated kind than what would be considered appropriate for foods, drugs or devices, and that the public is not actually deceived by the glamourous and exaggerated claims made in cosmetic advertising. A deception clause was considered to be unduly restrictive to the cosmetic industry, and would likely result in the legislation being honored in its breach rather than its observance.[8] The current wording of Sections 5, 9 and 20 is the same as appeared in the 1953 Act.

2.1.2 Supplementary Regulation to Sections 5, 9 and 20

Because of sub-sections (2) in Sections 5, 9 and 20 of the Act, all regulations pertaining to the labelling and/or packaging of foods, drugs and medical devices are relevant to the issue of deception. The regulations are too numerous to reproduce in this document but are found in the Food and Drugs Regulations in Parts A, B, C, D, E, G, J, and in the Medical Devices Regulations.

Sub-sections (2) of Sections 5, 9 and 20 do not deal with cosmetics, but Section 16 of the Cosmetic Regulations states:

16. No person shall sell a cosmetic unless it is labelled in accordance with these Regulations.

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[6] R.S.C. (1927), c. 76.

[7] Canada's Food and Drug Laws, R.E. Curran, Part VII, 1953-1954, p. 1060.

[8] Canada's Food and Drug Laws, R.E. Curran, Part VII, 1953-1954, p. 1061.

2.1.3 Supplementary Legislation to Sections 5, 9 and 20

2.1.3.1 *Criminal Code*

Section 408. of the *Criminal Code* describes a number of offenses similar to those described in Sections 5, 9 and 20 of the *Food and Drugs Act*. The *Criminal Code* describes these offenses as "passing off", and covers amongst other things foods, drugs, devices, cosmetics and consumer goods:

> *408. Every one commits an offense 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; or*
> *(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.*[9]

While the range of offenses covered by Section 408 of the *Criminal Code* and Sections 5, 9 and 20 of the *Food and Drugs Act* are similar, the language used in the *Food and Drugs Act* is more specific to the nature of the offenses covered. Since the *Criminal Code* must cover a wide range of situations, the language it uses is quite general.

2.1.3.2 *Competition Act*

The *Competition Act* is another federal statute which contains important provisions to deal with deceptive practices in commercial transactions. The original Section 52 of this Act which prohibited the making of false or misleading representations in general, also prohibited certain specific activities, such as claiming certain attributes for a product that were not supported by adequate tests, or making representations concerning warranties or guarantees where there was no reasonable prospect that they would be fulfilled. In 1999, during a major revision of the Act, Section 52 was amended to provide that a criminal offence would be established only if (see underlined below):

> ***Part VI - Offence in Relation to Competition***
>
> *52. (1) No person shall, <u>for the purpose of promoting</u>, directly or indirectly, the supply or use of a product or for the purpose of promoting, directly or indirectly, any <u>business interest</u>, by any means whatever, <u>knowingly or recklessly</u> make a representation to the public that is false or misleading in a material respect.*
>
> *(1.1) For greater certainty, in establishing that subsection (1) was contravened,*

[9] David Watt and Michelle K. Fuerst; The Annotated 1995 Tremeear's *Criminal Code*, Carswell Thompson Professional Publishing, 1994.

it is not necessary to prove that any person was deceived or misled.

(1.2) For greater certainty, a reference to the making of a representation, in this section or in section 52.1, 74.01 or 74.02, includes permitting a representation to be made.

Section 52 goes on to describe what kinds of representations would be caught by the prohibition, i.e., claims found on a product's wrapper, on an in-store sign or display, claims made during telephone solicitations, etc., and concludes by providing large fines and imprisonment for up to five years for those violating the provision.

Part VII of the Act also contains special provisions to deal with deceptive marketing practices. This part of the *Competition Act* provides that the Competition Bureau or Federal Court can impose a fine on an individual or corporation that engages in deceptive marketing practices and has the authority to order them to stop engaging in such activities. Finally, Section 36 allows any person to institute a legal action for loss or damage suffered as a result of activities prohibited by Part VI of the Act - Section 52 is found in Part VI. Up to now, criminal sanctions have not proven to be the most effective means of preventing misleading advertising, and that is why the 1999 amendments added a civil option to deal with the practice.

2.1.3.3 *Consumer Packaging and Labelling Act*

Another statutory provision that deals with the proper and safe labeling of consumer products is Section 7 of the *Consumer Packaging and Labeling Act*, which states:

7. (1) No dealer shall apply to any prepackaged product or sell, import into Canada or advertise any prepackaged product that has applied to it a label containing any false or misleading representation that relates to or may reasonably be regarded as relating to that product.

(2) For the purpose of this section, "false or misleading representation" includes

(a) any representation in which expressions, words, figures, depictions or symbols are used, arranged or shown in a manner that may reasonably be regarded as qualifying the declared net quantity of a prepackaged product:

(b) any expression, word, figure, depiction or symbol that implies or may reasonably be regarded as implying that a prepackaged product contains any matter not contained in it or does not contain any matter in fact contained in it; and,

©) any description or illustration of the type, quality, performance, function, origin or method of manufacture or production of a prepackaged product that may reasonably be regarded as likely to deceive a consumer with respect to the matter so described or illustrated.

The provisions of the *Consumer Packaging and Labelling Act*, including Section 7, apply to every product in the market place, with the notable exception of drugs and medical devices, which are specifically excluded.

2.2 Issue Analysis

When examining Sections 5, 9 and 20 of the *Food and Drugs Act*, the following issues are

raised:

2.2.1 Necessity of a Deception Clause Today and in the Future

All interested parties, whether they represent industry, public interest groups, academia or health professionals agree that misleading or false claims or advertising should not be allowed. The expectation of consumers that the products they purchase (foods, drugs, devices, consumer goods, etc.), are labelled, packaged, treated, processed, sold and advertised in a manner that is not false, misleading or deceptive is reasonable and generally recognized. The prohibitions contained in Sections 5, 9 and 20 are certainly relevant today and will continue to be relevant well into the future.

2.2.2 Concision and Clarity

When compared to foreign legislation, (see Section 2.4 below), it is immediately apparent how well Sections 5, 9 and 20 of the Act are written. They convey the same information in a few words that others have taken pages to express.

2.2.3 Product Status Problem

The first thing that has to be done in order to determine if a violation of Sections 5, 9, or 20 has been committed is to determine whether the product is a food, a drug or a device. This is often a problem for fringe products (products that are on the edge of a definition) or for products that are not considered to be foods, drugs or devices by their promoters. The advantage of the deception clause in the proposed Canada's Health Protection Act is that since the Act will apply to all products, product status is no longer relevant. A commodity simply has to meet the definition of a "product" for the provision to apply.

2.2.4 Subjectivity of the Deception Provisions

Enforcement actions under this Section are not necessarily straight forward. Whether a product's label, package, etc. is false is a relatively straight forward matter and could be proved easily. Whether a product's label, package, etc. is misleading, deceptive or likely to create an erroneous impression is more difficult to demonstrate. Sometimes, cases may have to be referred to the courts for a decision, which is a resource intensive and lengthy process. Section 6A (currently Section 3 of the *Food and Drugs Act*) was added in 1934 to deal to some extent with the "misleading, deceptive or likely to create an erroneous impression" component of Section 9 (see the Issue Paper on "Schedule A").

The deception provision should describe as much as possible violations that are clear, blatant, and non-subjective, so that there is minimal need for interpretation by the court. An example of non-subjective violation would be a breach of the requirement to have valid data to support any health claim prior to making the claim. The criteria to determine what is "valid data" could be provided in the regulations or in policy.

2.2.5 Implications of Section 3 and Schedule A on the Deception Provisions

Several initiatives (Health Protection Branch Regulatory Review, House of Commons Standing Committee on Health, etc.) have recommended that Schedule A be reviewed.

One possible result of the review of Schedule A would be the establishment of clear criteria for the inclusion of diseases on Schedule A. In the event diseases are removed from Schedule A, inspectors would only have the deception provisions to rely upon to obtain compliance when faced with certain questionable health claims in relation to these diseases. Strengthened deception provisions would then be needed to deal with these claims (see Issue Paper on "Schedule A").

2.2.6 Ticketing Scheme

As mentioned above, Sections 5, 9, and 20 are clear and concise, but their subjectivity creates a lot of work for the Department and enforcement under these Sections is not always resource effective. It has been suggested that if the deception provision was to describe clear, blatant and non-subjective violations, a resource effective enforcement measure, such as ticketing, could be used.

The ticketing scheme that currently exists under the *Contravention Act* is designed to be used for more routine and less serious offences. Perhaps a violation of a labelling requirement is an example of an infraction that could be subject to a ticket and a fine. The appropriateness of using a ticketing scheme could be explored as the regulations are developed.

2.2.7 Prohibition Against Publishing Deceptive Material

In addition to prohibiting the promotion of a product in a deceptive fashion, the legislation could make it a violation to publish (broadcast, print, post) misleading material, similar to Section 31 of the *Tobacco Act*. It could prohibit a person from publishing an advertisement once that person has been informed the ad is deceptive.

2.2.8 No Deception Provision for Consumer Products in Current Act

There is currently no deception provision for consumer products other than food, drugs and medical devices, in the legislation administered by Health Canada. Deception with respect to consumer products is dealt with by the Competition Bureau of Industry Canada. Cases of misleading representation of a product can be referred to their attention for action, but are processed according to their priorities. It is felt that the health protection legislation should have a deception prohibition for consumer products when health and safety are an issue.

2.2.9 No Deception Provision for Cosmetics in Current Act

In 1953, when the Act was extensively revised, a deception prohibition was not considered necessary for cosmetics, because it was felt the public was not deceived by exaggerated cosmetic advertising[10] and because the deception element could always be taken care of

[10]Canada's Food and Drug Laws, R.E. Curran, Part VII, 1953-1954, p. 1061.

under the authority of Section 24, the then regulation making Section[11]. In fact, the deception prohibition has applied to cosmetics all along, because when unacceptable claims are made for a cosmetic, it is considered to be a drug or a medical device so that Sections 9 or 20 can apply. The health protection legislation should have a deception prohibition that also applies to cosmetics, but it should be limited to the health and safety implications of any claim.

2.2.10 Deception Section in the Food Bill

The current Section 5 in the *Food and Drugs Act* was reworked as Section 19 in the Food Bill C-80), but it died, along with the rest of the Bill, when Parliament was prorogued. It had read:

> *19. (1) No person shall label, package, treat, process or sell any food, agricultural or aquatic commodity or agricultural input, or distribute any food free of charge, in a manner that is false, misleading or deceptive or that is likely to create an erroneous impression.*
>
> *(2) Any food that is labelled or packaged contrary to the regulations is deemed to be labelled or packaged in a manner that contravenes subsection (1).*

The words "regarding its character, value, composition, merit or safety" , as now found in Section 5 of the *Food and Drugs Act* after "erroneous impression ", were intentionally left out of Section 19 of the Food Bill. They were seen as limiting the application of the Section.

2.2.11 Deception Limited to Health and Safety Implications

Economic frauds, or any deception not related to health and safety , such as contents, taste, etc., are covered by other legislation as mentioned above, i.e. the *Criminal Code*, the *Competition Act* and the *Labelling and Packaging Act*. It is felt frauds and misleading representations not related to health and safety are not the in the realm of Health Canada, who's purpose, in the area of health protection, should be to protect the health of Canadians and to adhere to the "primacy of health and safety" as a principle. In other words, health and safety should be the primary consideration in actions taken by the Department. In addition, preventing deception clearly falls under criminal law power, particularly when it relates to health and safety.

The new Canada's Health Protection Act should have a deception prohibition that only affects representations as they relate directly or indirectly to health and safety. Whether a claim is related directly or indirectly to health and safety would be determined by whether the product's claim is covered by any of the definitions described in the Act. For example, if a product claims that it will promote hair growth, such a claim would be considered to be related to health and safety because it modifies a physiological function.

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[11] Canada's Food and Drug Laws, R.E. Curran, Part VII, 1953-1954, p. 1077.

Claims with respect to the composition of a product would also be covered as they are clearly health and safety related.

2.2.12 Supporting Data/ Standard of Evidence

There was general agreement among interested parties, regardless of their affiliation, that health claims made for products should be truthful. One of the ways for a supplier to demonstrate that a health claim for a product is valid is to have data to substantiate the alleged claim. The Canada's Health Protection Act could have a requirement for suppliers to be able to produce valid data to support a health claim at the time the claim is made. While the pharmaceutical industry is experienced with supporting claims with sound clinical or scientific data, other segments of the industry, e.g., natural health products, cosmetics, consumer products might not adapt to this concept as easily.

The subject of supporting data raises the issue of standards of evidence. What type of data should be produced for what type of products and for what type of claims? There is general agreement that the standard of evidence should vary depending on the degree of risk. Some interested parties maintain that today, product claims are evaluated based on science, and that because of this rigorous standard, a decision as to whether something is misleading is less likely to have to be referred to the courts. However, others believe that alternative products like herbal medicines and homeopathic medicines should not be assessed using the same standard of evidence than that used for conventional medicines. They say that evidence of historical/traditional use should be accepted to support the efficacy of these products.

The requirement to have valid data to support a claim at the time it is made is an example of a non-subjective deception provision as discussed earlier in section 2.2.4 of this paper. The criteria to determine what is "valid data" could be provided in regulations or in policy. The consequence of such a provision is that the absence of data is a violation in itself, which would be a radical change from the current situation.

In addition, the data to support a claim as it relates to the safety of a product or its effect on health would have to be made available to the public, to the extent reasonably possible and subject to protecting confidential information.

2.2.13 Onus on Supplier to Demonstrate the Claim

Precious resources are wasted when the Department has to prove that a health claim is false and misleading in order to justify a corrective action. The onus should not be on the Department to demonstrate that a claim is false or misleading. The responsibility should reside with the supplier to provide evidence to substantiate the claim.

With the current legislative framework, the burden of proof is on the Department, except when there is a clear violation of a regulatory standard. The proposed Act could have a provision, within the deception prohibition, to shift the burden of proof on the supplier. If a supplier makes a health claim for a product, the claim should be true, and the supplier

should have evidence to support it. The absence of valid data to support the claim would in itself be a violation: the Department would not have to demonstrate that the claim is false.

It is worth noting again that the *Competition Act* also shifts the burden of proof onto the person making the representation:

> *74.01(1) A person engages in reviewable conduct who, for the purpose of promoting, directly or indirectly, the supply or use of a product or for the purpose of promoting, directly or indirectly, any business interest, by any means whatever,*
>
> *(a) makes a representation to the public that is false or misleading in a material respect;*
>
> *(b) makes a representation to the public in the form of a statement, warranty or guarantee of the performance, efficacy or length of life of a product* ***that is not based on an adequate and proper test thereof, the proof of which lies on the person making the representation****; or,...*

2.2.14 Drinking Water Materials Safety Bill

It has been suggested that the wording of the proposed sections on deception in the Drinking Water Materials Safety Bill be considered. Their wording has merits and should be considered at the time of drafting the new Health Protection Bill. They read:

> *10. No person who manufactures, imports or sells a drinking water material shall make any representation that is false, deceptive or misleading, or is likely to create an erroneous impression, regarding*
>
> *(a) its character, composition, manufacture, value, quantity, performance, merit, safety or intended use;*
> *(b) its conformity with any standard prescribed by the regulations*
> *©) its certification.*
>
> *11. No person shall, for the purpose of selling a drinking water material, make any representation that is false, deceptive or misleading, or is likely to create an erroneous impression, regarding the composition, characteristics or properties of water.*
>
> *12. No person who manufactures, imports or sells a drinking water material shall make any representation*
>
> *(a) regarding its effect on water or on human health, or*
> *(b) regarding the effect on human health of water that comes into contact with or that is, or is purported to be, modified by the drinking water material, unless the person is able to support the representation with the results of tests designed and conducted in accordance with commonly accepted scientific principles, which results were obtained before the representation was made.*

2.3 Consultations

All interested parties, whether they represent industry, public interest groups, academia or health professionals agree that misleading or false claims or advertising should not be permitted. Consumers demand that the products that they purchase (foods, drugs, devices, consumer goods, etc.), are labelled, packaged, treated, processed, sold or advertised in a manner that is not false, misleading or deceptive.

2.4 International Comparison

Australia, the United States and United Kingdom all have provisions in their drug legislation that have the same or a similar effect as Sections 5, 9, and 20 of the *Food and Drugs Act*.

2.4.1 United States

In the United States a statutory definition of misbranding appeared as Section 8 of the Federal *Food and Drugs Act* of 1906. The term was used to describe a number of offenses related to false or misleading labelling. Today, Section 502 of the United States' *Federal Food, Drug and Cosmetic Act* lays out the conditions under which drugs and devices are considered to be misbranded.

According to Pugsley[12] when Canadian drafters were writing the *Food and Drugs Act* in 1920, they borrowed the offense of misbranding from the 1906 US legislation. While Canada has since dispensed with using the term misbranding, because it was not truly descriptive of the offenses included in the definition[13], the US has continued to use it. The US definition of misbranding now runs to several pages and covers many of the same offenses as Section 9 of the *Food and Drugs Act*. Parts of the US definition of misbranding similar in effect to Section 9 of the *Food and Drugs Act* are;

> *Sec. 502. [352]. Misbranded Drugs and Devices*
>
> *A drug or device shall be deemed to be misbranded -*
>
> *(a) If its labelling is false or misleading in any particular.*
>
> *(b) If in a package form unless it bears a label containing (1) the name and place of business of the manufacturer, packer, or distributor; and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count: Provided, That under clause (2) of this paragraph reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the Secretary.*
>
> *©) If any word, statement, or other information required by or under authority of this Act to appear on the label or labelling is not prominently placed thereon with such conspicuousness (as compared to other words, statements, designs, or devices, in the labelling) and in such terms as to render it likely to be read and understood by the ordinary individual under*

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

[13] Supra note 10, p.424.

customary conditions of purchase and use.[14]

It is interesting to note that while Canada borrowed the offense of misbranding from the 1906 US legislation, the 1906 US legislation was based on the earlier English legislation "*The Sale of Food and Drugs Act*, 1875.".[15] This came about because of a competition held in 1880 by the US National Board of Trade (later to become the US Chamber of Commerce) in which they offered a prize of $1000 for the best three drafts of a national food adulteration statute. The prize was won by a public analyst in England who based his draft statute on the English legislation of 1875. Although the wording was changed, all the elements of adulteration and misbranding in the draft statute ultimately became part of the US Federal *Food and Drugs Act* of 1906.

2.4.2 Australia

The Australian *Therapeutic Goods Act* (TGA) contains provisions similar in intent to Section 9 of the Canadian *Food and Drugs Act*.

> *(5) For the purposes of this Act, the presentation of therapeutic goods is unacceptable if it is capable of being misleading or confusing as to the content or proper use of the goods and, without limiting the previous words in this subsection, the presentation of therapeutic goods is unacceptable:*
>
> > *(a) if it states or suggests that the goods have ingredients, components or characteristics that they do no have; or*
> > *(b) if a name applied to the goods is the same as the name applied to other therapeutic goods that are supplied in Australia where those other goods contain additional or different therapeutically active ingredients; or*
> > *©) if the label of the goods does not declare the presence of a therapeutically active ingredient; or*
> > *(d) if a form or presentation of the goods may lead to unsafe use of the goods or suggests a purpose that is not in accordance with conditions applicable to the supply of the goods in Australia; or*
> > *(e) in prescribed cases.*[16]

The wording of this section is quite different from Section 9 of the *Food and Drugs Act* but a similar range of offenses are covered. Other sections of the Australian TGA prohibit the representation of a number on the label of a therapeutic good as a registration number unless it actually is a valid registration number[17], and declares a drug to be non-compliant

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[14]Compilation of Food and Drug Laws, Volume 1, The Food and Drug Law Institute Series 1995 Edition.

[15]Hutt, Journal of the Association of Food and Drug Officials, Vol. 68, No. 3, September 1996.

[16]*Therapeutic Goods Act*, 1989

[17]Supra note 11, Section 22.

with the Pharmacopoeial standard if it is not labelled in accordance with the standard.[18]

2.4.3 United Kingdom

The British *Medicines Act* of 1968 contains several provisions having a similar effect to Section 9 of the *Food and Drugs Act*. They provide very broad consumer protection among the more important provisions are:

> *64. Protection of purchasers of medicinal products*
>
> *(1) No person shall, to the prejudice of the purchaser, sell any medicinal product which is not of the nature or quality demanded by the purchaser.*[19]
>
> *65. Compliance with standards specified in monographs in certain publications*
>
> *(1) No person shall, in the course of a business carried on by him,*
>
> *(a) Sell a medicinal product which has been demanded by the purchaser by, or by express reference to, a particular name, or*
>
> *(b) sell or supply a medicinal product in pursuance of a prescription given by a practitioner in which the product required is described by, or by express reference, to a particular name,*
>
> *if that name is a name at the head of the relevant monograph and the product does not comply with the standard specified in that monograph.*[20]
>
> *85. Labelling and marking of containers and packages*
>
> *(1) The appropriate Ministers may make regulations imposing such requirements as, for any of the purposes specified in subsection (2) of this section, they consider necessary or expedient with respect to any of the following matters, that is to say-*
>
> *(a) the labelling of containers of medicinal products;*
> *(b) the labelling of packages of medicinal products;*
> *©) the display of distinctive marks on containers and packages of medicinal products.*
>
> *(2) The purposes referred to in the preceding subsection are*
>
> *(a) securing that medicinal products are correctly described and readily identifiable*
> *(b)securing that any appropriate warning or other appropriate information or instruction is*

[18] Supra note 11, Section 13

[19] *Medicines Act* 1968

[20] Ibid

given, and that false or misleading information is not given, with respect to medicinal products;
©) promoting safety in relation to medicinal products.

(3) No person shall, in the course of a business carried on by him, sell or supply, or have in possession for the purpose of sale or supply, any medicinal product in such circumstances as to contravene any requirements imposed by regulations under this section which are applicable to that product.

(4) .....

(5) Without prejudice to the preceding provisions of this section, no person shall, in the course of a business carried on by him, sell or supply, or have in his possession for the purpose of sale or supply, a medicinal product of any description in a container or package which is labelled or marked in such a way that the container or package

(a) falsely describes the product, or
(b) is likely to mislead as to the nature or quality of the product or as to the uses or effects of medicinal products of that description.[21]

Section 85 provides authority to make regulations pertaining to labelling (sub-section 1), makes it an offense to contravene the labelling regulations (sub-section 3) , and makes it an offense to misrepresent the product (sub-section 5).

Section 86 of the British *Medicines Act* is almost the same as Section 85 except it is applicable to leaflets that are supplied, or are intended to be supplied, with medicinal products.

Section 93 prohibits false or misleading advertising.

93. False or misleading advertisements and representations

(1) Subject to the following provisions of this section, any person who, being a commercially interested party, or at the request or with the consent of a commercially interested party, issues, or causes another person to issue, a false or misleading advertisement relating to medicinal products of any description shall be guilty of an offense.[22]

Other Sub-sections of Section 93, not reproduced above, specify in greater detail under what circumstances an offense has been committed.

2.5 World Health Organization

The WHO Ethical Criteria for Medicinal Drug Promotion was adopted by the 41st World

[21] Ibid

[22] Ibid

Assembly on May 13, 1988, and it provides that "advertisements may claim that a drug can cure, prevent, or relieve an ailment only if this can be substantiated".[23]

2.6 Impact on Department/ Resources

Since the deception prohibition would apply to all products as opposed to only food, drugs and medical devices, suppliers would no longer try to demonstrate that their product does not meet the definition of a drug, for example, to escape the application of the provision. This would facilitate the work of field inspectors.

If considered as a viable option when the regulations are developed, a ticketing scheme would also be a resource effective enforcement measure.

2.7 Impact on Government

With respect to the fact that the deception prohibition would now be limited to health and safety implications, the impact would be negligible. With regard to food, the Canadian Food Inspection Agency (CFIA) is already responsible for the non-health related standards. As to other products, it should not increase the burden of Industry Canada as they are already responsible for deception for all products under the *Competition Act*.

2.8 Impact on Interested Parties

It will not be possible for industry to raise the issue of product status in an attempt to avoid the deception prohibition. By the same token, as precious time will not be wasted clarifying the status of products, corrective action will be taken in a more timely fashion and Canadians will be better protected from deception.

Although the pharmaceutical industry is experienced with supporting its claims with sound clinical or scientific data, the requirement to have data to substantiate claims might not receive a warm reception from other segments of the industry, e.g., natural health products, cosmetics, consumer products, etc.

2.9 Legal Considerations

Preventing deception clearly falls under criminal law powers, particularly when it relates to health and safety.

3. OPTIONS ANALYSIS

Option 1: No Deception Provision in the Canada's Health Protection Act

There has been no mention of a desire to eliminate the deception provision. There is a common agreement that false or misleading representation of products should not be allowed, and that the proposed Canada's Health Protection Act should contain a deception provision along the lines of Sections 5, 9 and 20.

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[23] World Health Organization, Ethical Criteria for Medicinal Drug Promotion, May 13, 1988.

Option 2: Status Quo: Keep Sections 5, 9 and 20
Sections 5, 9 and 20 of the *Food and Drugs Act* are relevant, useful and reasonable. While in some cases relying on these Sections for compliance purposes could result in problems, they have significant merit. When compared to the wordy sections of foreign legislation, the broad scope of these Sections, accomplished with a clear, simple language, has to be appreciated. However, this option does not include cosmetics or consumer products, and also does not address the product status problem, i.e. perpetuates the categorization of commodities as either food, drugs or devices for the provision to apply.

Option 3: Revise Sections 5, 9, and 20 of the *Food and Drugs Act*
While the general prohibitions of the Sections should be retained, consideration should be given to cover cosmetics and all consumer products by using the term "product", which would need to be defined in the Act. The deception prohibition should be limited to health and safety implications, and should also include a provision that would shift the onus onto the manufacturer to substantiate the claims made for its product.

The drafting instructions could read as per the following:

- As it relates directly or indirectly to health and safety, no supplier shall manufacture, promote or market a product in a way that may cause the purchaser or the person using the product, to be misled as to the characteristics, value, safety and effectiveness of the product or as to its conformity with any standard prescribed by the regulations or any other standard or requirement.

  The focus of this proposed Act would be on health protection. Deception which does not relate directly or indirectly to health and safety would be dealt with through other already existing federal or provincial legislation. However, any matter which may affect health and safety in one way or the other would be captured.

- No supplier shall label, package, promote or market a product contrary to the proposed Act or regulations.

- It is for the person who makes the claim to demonstrate its truthfulness based on science and objective observation.

- No person shall make a claim that relates to the safety of a product or its effect on health unless, at the time the claim is made and at any time thereafter, the person can provide Health Canada with valid data to support the claim.

  Regarding the two above paragraphs, it should be noted that while such provisions are not found in the current health protection legislation, the Competition Act (administered by the Competition Bureau of Industry Canada) provides that:

> *"74.01 (1) A person engages in a reviewable conduct who, for the purpose of promoting, directly or indirectly, the supply or use of a product or for the purpose of promoting, directly or indirectly, any business interest, by any means whatever,*
> *(a) make a representation to the public that is false or misleading in a material respect;*
> *(b) make a representation to the public in the form of a statement, warranty or guarantee of the performance, efficacy or length of life of a product that is not based on an adequate and proper test thereof, the proof of which lies on the person making the representation ...".*
>
> *The proposed Act would borrow some of the provisions of the Competition Act with regard to deceptive practices.*

- The manufacturer must make available to the public, a meaningful summary of the data in support of a claim that relates to the safety of a product or its effect on health to the extent reasonably possible and subject to protecting confidential information.

  Administrative guidelines and regulations would provide direction as to how to comply with this requirement. For example, the summary of the data would have to be pre-approved by Health Canada with regard to certain classes of products.

- The proposed Act would make it an offence for public media to disseminate an advertisement when it knew or ought to have known that the promotion contravened the Act or the regulations.

  This would apply for example in a case where a newspaper has been notified by Health Canada that a promotion is illegal but nevertheless continues to publish the advertisement.

- The above provisions would apply to any representation which could be interpreted by the consumer to relate directly or indirectly to health and safety.

  For example, a representation to the effect that the use of a water treatment device will improve the purity of drinking water would be covered because the consumer would likely understand that this could translate into a health benefit.

Such a provision extends the prohibition on false representation related to safety and health to cosmetics and consumer products. It also addresses the product status problem discussed above: a product does not have to be considered a food, a drug or a device for

a misleading claim to be covered by the Act. For example, for the current Section 9 to apply, the commodity has to be considered a “drug”, which makes it more difficult for products which are not considered drugs by their promoters (e.g., natural health products). For the above provision to apply, the product simply has to meet the definition of a “product”.

With such a provision, failure to have the supporting valid data would be a clear violation immediately subject to corrective action. The provision also shifts the onus of proof on the supplier making the claim and makes it illegal for a person who has been advised that an advertisement is deceptive to publish it.