HISTORICAL BACKGROUND

The current Canadian Food and Drugs Act evolved as a result of the growth of the drug manufacturing industry. The Canadian Proprietary or Patent Medicines Act was first passed in 1909. This act was intended to control formulations that contained addictive and toxic substances such as, cocaine, opium, strychnine and alcoholic preparations claiming to be “medicines.” By the 1900’s, the addictive or poisonous nature of many substances was becoming known and an effort was being made to protect the public from undue harm. In 1919, amendments to the Act prohibited claims to cure specific diseases and false, misleading or exaggerated claims on labels and in advertising.

A new Act, the Proprietary or Patent Medicine Act of 1923, required products containing pharmacopeial ingredients to be registered with the Department of Commerce. Product labels had to declare ingredients and products containing alcohol without sufficient medicinal ingredients were prohibited. Many questionable products and “secret formulations” were therefore removed from the Canadian market by 1925.

Pharmacopeial ingredients, both non-narcotic and narcotic, were now being regulated under separate Acts. The Food and Drugs Act and the Opium and Narcotic Control Act were first passed in 1920. Early Canadian Food and Drug legislation was concerned primarily with adulteration. A statutory definition of misbranding (incorrect identification) was introduced to the Food and Drugs Act in 1920 but applied only to food. Misbranding was extended to drugs in 1927. Most offenses that were deemed to constitute misbranding were related to fraud (representing the product as something it was not).

In 1934, Section 3 and Schedule A were added to the Food and Drugs Act. Section 3 prevents the dissemination of information, through any form of advertising about treatments, preventatives, or cures for Schedule A diseases. Schedule A lists diseases which can only be properly diagnosed and treated by a physician, or for which there is no known treatment. These additions were made to:

1. Prohibit the advertisement and sale of treatments for conditions where no treatment is known to medical science,
2. Prohibit the advertisement and sale of treatments where self-treatment is not considered proper or safe,
3. Encourage people to seek medical attention for serious conditions,
4. Prevent fraud.

At this time false or misleading claims for any product were regulated under Section 7 which stated that “Food or drug shall be deemed to be misbranded within the meaning of this Act ... (e) if false or exaggerated claims are made for it upon the label or otherwise.” These are the strong anti-fraud elements in the Act.

An important feature of Section 3 is, that it is unnecessary for the regulator to prove a drug is unsafe, valueless, harmful, or that the advertising is false or misleading for one of the listed conditions. Proof for safety and efficacy must be provided by the claimant. This section is an outright prohibition on representations for treatment of Schedule A diseases without proper evidence (see below).

In 1937, the S. E. Messengill Company of Bristol, Tennessee, in the United States marketed an Elixir...
Sulfanilamide consisting of 8.8% of the drug in 72% diethylene glycol. This product, intended for Southerners who liked to drink their medicines, was tested only for flavor prior to marketing. Unfortunately, the poisonous nature of the solvent was not recognized. The resulting 105 deaths from acute kidney failure caused a public outcry and precipitated the passage of legislation which demanded that medicinal products be tested to ensure their safety. Canada followed suit and safety standards were strengthened.

The Food and Drugs Act was again debated in 1953 with reference to the advertisement of treatments and cures for cancer. In discussing Schedule A in Parliament, R. E. Curran, MP, stated that Schedule A lists conditions which “have been found fruitful sources of revenue for the quack and the charlatan.”

The message was clear to those contemplating the marketing of any quick quack cures to vulnerable individuals. Schedule A remains, and has been periodically amended to remove conditions, for example, scabies (1988), tuberculosis (1992) and pneumonia (1992), as effective treatments have become available. It continues to list diseases for which self-diagnosis and self-treatment are not in the best interests of the general public, for example, arthritis, cancer and diabetes.

The 1960’s were important years for changes in regulation as a result of one substance. In 1953, thalidomide, a sedative developed by Chemie Gruenthal G.m.b.H. in Germany, was widely marketed in Europe and identified in 1962 as a potent teratogen. In 1962 the Food and Drugs Act was amended governing the sale of new drugs and restricting the availability of investigational drugs. Therapeutic products now had to provide scientific data to substantiate quality, safety and efficacy before they were granted a Drug Identification Number (DIN) and released.

Section 10 of the Food and Drugs Act replaced the corresponding section in the Proprietary or Patent Medicines Act concerning labeling and registration of products. All medicinal products for general sale were now required to have a complete quantitative listing of ingredients on the label. The Proprietary or Patent Medicines Act was dropped altogether in 1977. Today, the Food and Drugs Act regulates the sale of food, cosmetics, medical devices, prescription and non-prescription products in Canada. The Controlled Drugs and Substances Act of 14 May 1997 now controls the manufacture, distribution and sale of control drugs and substances listed in the Schedule to the Act.

THE HERBAL REMEDY REVIVAL

By the end of the 1970’s proprietary and patent medicines had all but disappeared from the market. Esoteric concoctions of herbs, roots and animal extracts used as blood purifiers and cure all’s peddled by snake oil salesmen seemed to be a matter of the past. The last thing a “businessman of medi-
can be provided to the consumer in the form of promotional literature. This is a flagrant violation of the Food and Drugs Act. This violation is not effectively enforced because of the scope of the problem and the lack of recognition by the public of the deception.

In 1985 an Expert Advisory Committee on Herbs and Botanical Preparations was formed to make recommendations with respect to regulating these products. In 1986 The Health Protection Branch (HPB) issued an information letter (704) and asked manufacturers to comply with Good Manufacturing Practices (GMP's). An examination of many products revealed that some were contaminated by, for example, ground glass and bacteria. An adherence to GMP's would ensure a clean product. However GMP's do not include scientific proof of efficacy and, therefore, the efficacy of the product is still in question. Because many natural substances are toxic the HPB listed 34 toxic herbs as food adulterants and prohibited their use.

In 1989 the HPB circulated Information Letter 705 in which 57 herbs and substances were to be regulated as food adulterants. In October 1995, after reviewing the earlier reports (1985, 1993) from the Expert Advisory Committee, the Health Canada Drugs Directorate Guideline: Traditional Herbal Medicines was issued. This guideline requires the manufacturer of herbal and natural products to:
1. Follow Good Manufacturing Practices,
2. Provide a complete quantitative listing of ingredients on the label, and
3. Supply a minimum of two traditional references to support the reputed pharmacological action for the part of the plant used.

A Drug Identification Number (DIN) is issued if the product is compliant. A DIN ensures a safe, quality product. However, the claim for efficacy is not supported by scientific evidence, which requires double blind controlled studies. Therefore, efficacy of the product remains in question.

On 12 April 1997, Health Canada announced its new regulations for natural products. Anyone, manufacturing, distributing, importing or selling such products would require establishment licenses and pay a fee for each item sold. All applicants would have to pay $720 initially, then $500 annually on each approved item. Fees would be capped at 1.5% of annual revenues. Good Manufacturing Practices would become mandatory and premises would have to be open to inspection.

Consumer groups and health freedom lobbyists were outraged over the announcement. It was claimed that this was a conspiracy by the government to skew control and profits into the arms of the pharmaceutical giants. An Advisory Panel on Natural Health Products was formed in June 1997 to make recommendations to the Standing Committee on Health, which would report to the Government in the fall of 1998. A moratorium on establishment licenses and fees was announced in September 1997 until the Standing Committee on Health tabled its report.

The report of the Standing Committee on Health was tabled in November of 1998 and made 53 recommendations to the government. On the 26th March 1999, Minister of Health, Alan Rock announced that the federal government would spend $7 million over 3 years to establish a new regulatory regime for herbal remedies and other natural health products.

The new Office of Natural Health Products will monitor manufacturers to ensure that they follow Good Manufacturing Practices and provide full disclosure on the product label. A further $3 million will be spent to fund research into natural health products. Why this funding is not going to be through the Medical Research Council, an already established national research body, is not explained. Nor is the most important question, “What constitutes evidence for efficacy with respect to herbal remedies and natural health products?”

Many other questions about how the new system will work will be left to the expert advisory committee that Mr. Rock says he will establish. The composition of this committee has not been announced.

In the meantime, “food” and “health supplements” continue to be sold with health claims, some for Schedule A diseases.